ARMY RDT&E BUDGET ITEM JUSTIFICATION (R2 Exhibit)

February 2004

BUDGET ACTIVITY
2 - Applied Research

PE NUMBER AND TITLE
0602787A - MEDICAL TECHNOLOGY

	COST (In Thousands)	FY 2003 Actual	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate
	Total Program Element (PE) Cost	120935	174501	60877	69782	67732	65938	64020
841	COMPUTER-ASST MINIMALLY INVASIVE SURGERY	2002	1355	0	0	0	0	0
845	BONE DISEASE RESEARCH PROGRAM	1001	0	0	0	0	0	0
863	BTLFLD SURGICAL REPLAC	4811	2905	0	0	0	0	0
865	CENTER FOR MILITARY BIOMATERIALS RESEARCH	952	1452	0	0	0	0	0
866	CLINICAL TRIAL PLEZOELECTRIC DRY POWDER INHALATION	1619	0	0	0	0	0	0
867	DIAGNOSTICS IN TRAUMATIC BRAIN INJURY BLOOD BASED	1430	969	0	0	0	0	0
869	T-MED/ADVANCED TECHNOLOGY	3105	3356	3378	3415	3512	3574	3641
870	DOD MED DEF AG INF DIS	26760	13838	15676	16366	16042	15983	16384
873	HIV EXPLORATORY RSCH	0	10881	10819	11270	11512	11475	11433
874	CBT CASUALTY CARE TECH	8487	8668	8469	16051	13838	11914	9148
878	HLTH HAZ MIL MATERIEL	11038	11521	12116	12140	12276	12404	12637
879	MED FACT ENH SOLD EFF	8515	8740	10419	10540	10552	10588	10777
953	DISASTER RELIEF & EMERGENCY MEDICAL SVC (DREAMS)	0	10650	0	0	0	0	0
968	SYNCH BASED HI ENERGY RADIATION BEAM CANCER DETECT	16909	22026	0	0	0	0	0
96A	EMERGENCY HYPOTHERMIA	2106	2226	0	0	0	0	0
96C	DIGITAL IMAGING AND CATHERIZATION EQUIPMENT	763	969	0	0	0	0	0
96D	ENDOBIOLOGICS VACCINATION PROGRAM	952	0	0	0	0	0	0
96E	HEMORRHAGE CONTROL DRESSING	2334	2905	0	0	0	0	0
96F	PORTABLE BIOCHIP ANALYSIS SYSTEM	1714	0	0	0	0	0	0
96G	PRE-CLINICAL AND CLINICAL EVALUATION	1619	0	0	0	0	0	0

96H	RUGGED TEXTILE ELECTRONIC GARMENTS	952	0	0	0	0	0	0
96I	REMOTE ACOUSTIC HEMOSTASIS	6670	3388	0	0	0	0	0
96J	GULF WAR ILLNESS	2857	0	0	0	0	0	0
MA1	ARTHROPOD-BORNE INFECTIOUS DISEASE CONTROL	2002	0	0	0	0	0	0
MA2	DIABETES PROJECT	0	6536	0	0	0	0	0
MA3	MEDICAL AREA NETWORK FOR VIRTUAL TECHNOLOGY	3240	5712	0	0	0	0	0
MA4	SPEECH CAPABLE PERSONAL DIGITAL ASSISTANT	1905	0	0	0	0	0	0
MA5	CENTER FOR INTERNATIONAL REHABILITATION	3334	3388	0	0	0	0	0
MA6	DERMAL PHASE METER	1001	1162	0	0	0	0	0
MA8	MONOCLONAL ANTIBODY BASED TECHNOLOGY	0	1452	0	0	0	0	0
MA9	OPERATING ROOM OF THE FUTURE	2857	0	0	0	0	0	0
NA7	ADVANCED SURGICAL NAVIGATION (CA)	0	1743	0	0	0	0	0
NA8	IMPROVING SOLDIER PERFORMANCE (CA)	0	2324	0	0	0	0	0
NA9	BEHAVIORAL GENOMICS (CA)	0	1936	0	0	0	0	0
OA1	BIO-DEFENSE GENE KNOCKOUT TECHNOLOGY (CA)	0	2033	0	0	0	0	0
OA2	BIOMEDICAL ENG TECH AND ADV MATERIALS (CA)	0	969	0	0	0	0	0
OA3	CENTER FOR ADV SURGICAL & INTERVENTIONAL TECH (CA)	0	2033	0	0	0	0	0
OA4	CHRONIC MULTI-SYMPTOM ILLNESSES (CA)	0	4841	0	0	0	0	0
OA5	COMPUTATION PROTEOMICS (CA)	0	2905	0	0	0	0	0
OA6	CONJUGATE VACCINES TO PREVENT SHIGELLOSIS (CA)	0	1355	0	0	0	0	0

OA7	ELGEN GENE DELIVERY TECHNOLOGY (CA)	0	969	0	0	0	0	0
OA8	ENHANCED RES IN TRAUMA PREVENTION/TREATMENT/REHAB	0	1452	0	0	0	0	0
OA9	GENETIC ACUTE ENHANCED BIOWARFARE THERAPY PROG (CA	0	969	0	0	0	0	0
PA1	HEMOGLOBIN BLOOD OXYGEN CARRIER (CA)	0	969	0	0	0	0	0
PA2	LARGE-SCALE/POLYCLONAL/HUMAN ANTIBODY PRODUCTION	0	2905	0	0	0	0	0
PA4	WOUND HEALING PROJECT (CA)	0	3002	0	0	0	0	0
PA5	NANOFABRICATED BIOARTIFICIAL KIDNEY (CA)	0	2324	0	0	0	0	0
PA6	NATIONAL TISSUE ENGINEERING RESEARCH (CA)	0	969	0	0	0	0	0
PA7	NON-INVASIVE MEDICAL SENSORS (CA)	0	1452	0	0	0	0	0
PA8	NOVEL GROWTH FACTOR DELIVERY TECHNOLOGY (CA)	0	969	0	0	0	0	0
PA9	PROSTHETIC DEVICE CLIN EVAL AT WRAIR AMPUTEE CTR	0	2421	0	0	0	0	0
RA1	SLEEP DEPRIVATION RESEARCH AT WRAMC (CA)	0	1452	0	0	0	0	0
RA2	TARGETED NANOTHERAPEUTICS FOR CANCER (CA)	0	969	0	0	0	0	0
RA3	THERAPEUTIC VACCINES FOR BIOLOGICAL THREAT (CA)	0	969	0	0	0	0	0
RA4	TRANSPORTABLE PATHOGEN REDUCT AND BLOOD SAFETY SYS	0	1936	0	0	0	0	0
RA5	USAMRIID ANTHRAX RESEARCH (CA)	0	2421	0	0	0	0	0
RA6	VERSA HSDI (CA)	0	4115	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. Where feasible, it further seeks to exploit opportunities to enhance Current Force capabilities. 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 battlefields, areas of low-intensity conflict, and military operations other than war.

This program element funds research for core applied technology in the following focus areas: Infectious Diseases; Combat Casualty Care; Military Operational Medicine; and Health Hazards for Materiels.

Infectious Diseases: The main focus in Infectious Diseases is the medical protection against naturally occurring diseases of military importance. This is accomplished by identifying and developing methods for infectious disease prevention and treatment including vaccines, prophylactic and therapeutic drugs.

Combat Casualty Care: Focus of applied research for the care of trauma and burns due to battlefield injuries. Research in this PE includes: organ system survival, shock treatment resulting from blood loss and infection, blood preservation, and potential blood substitutes for battlefield care. Combat Dentistry focus is on the prevention and treatment of combat maxillofacial (face/neck) injuries and essential dental treatment on the battlefield.

Military Operational Medicine: Encompasses biomedical solutions that protect soldiers and enhance their performance in the face of multiple stressors in operational and training environments. Relevant core capabilities include; a problem solving orientation, and a human physiology research focus. Representative areas of research concern include insect repellent, sleep deprivation, and nutritional needs.

The cited work is consistent with Strategic Planning Guidance, the Army Science and Technology Master Plan, the Army Modernization Plan, and the Defense Technology Area Plan. 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; and the U.S. Army Aeromedical Research Laboratory, Fort Rucker, AL. The program element contains no duplication with any effort within the Military Departments.

NOTE: Due to database technical difficulties project X04, Molecular Genetics and Musculoskeletal Research, was left out of the resource table above. This particular project is a new FY 04 Congressional add of $8.5M. The correct program element total for FY 04 is 183,001.

B. Program Change Summary	FY 2003	FY 2004	FY 2005
Previous President's Budget (FY 2004)	124314	58877	61072
Current Budget (FY 2005 PB)	120935	174501	60877
Total Adjustments	-3379	115624	-195
Congressional program reductions		-1497	
Congressional rescissions			
Congressional increases		118350	
Reprogrammings	-3379	-1229	
SBIR/STTR Transfer			
Adjustments to Budget Years			-195

Change Summary Explanation: FY04 - Forty-six FY04 Congressional adds totaling $129,850 were added to this PE.

FY04 Congressional Adds with no R-2As:
($1,800) Advanced Surgical Navigation, Project NA7
($2,500) USAMRIID Anthrax Research, Project RA5
($2,000) Behavioral Genomics, Project NA9
($2,100) Bio-Defense Gene Knockout Technology Program, Project OA1
($1,000) Biomedical Engineering Technology and Advanced Materials, Project OA2
($2,100) Center for Advanced Surgical and Interventional Technology, Project OA3
($1,500) Center for Military Biomaterials Research (CeMBR), Project 865
($3,000) Chitosan Hemorrhage Control Dressing, Project 96E
($5,000) Chronic Multi-sympton Illnesses, Project OA4
($3,000) Computation Proteomics, Project OA5
($1,400) Conjugate Vaccines to prevent Shigellosis, Project OA6
($1,200) Dermal Phase Meter, Project MA6
($3,000) Development of Large-scale Polyclonal Human Antibody Production, Project PA2
($1,000) Diagnostics in traumatic Brain Injury - Blood Based, Project

867
($1,000) Digital Imaging and Catheterization Equipment, Project 96C
($1,000) Elgen Gene Delivery Technology, Project OA7
($2,300) Emergency Hypothermia, Project 96A
($1,500) Enhanced Research in Trauma Prevention, Treatment and Rehabilitation, Project OA8
($1,000) Genetic Reassortment by Mismatched Repair-Enhanced Acute Biowarfare Therapy Program, Project OA9
($1,000) Hemoglobin Blood Oxygen Carrier, Project PA1
($2,400) Improving Soldier Performance, Project NA8
($3,500) International Rehabilitation Network, Project MA5
($4,250) Joint Diabetes Project, Project MA2
($1,000) Marshall Island Diabetes Reversal / Wellness Program, Project MA2
($5,900) Medical Area Network for Virtual Technologies (MANVT), Project MA3
($1,500) Medical Vanguard for Diabetes Management, Project MA2
($1,400) Minimally Invasive Surgery Program for Ohio, Project 841
($8,500) Molecular Genetics and Musculoskeletal Research Program, Project X04
($1,500) Monoclonal Human Anti-Anthrax Toxin Antibodies Development, Project MA8
($2,400) Nanofabricated Bioartificial Kidney, Project PA5
($1,000) National Tissue Engineering Research, Project PA6
($1,500) Non-Invasive Medical Sensors, Project PA7
($1,000) Novel Growth Factor Delivery Technology, Project PA8
($2,500) Prosthetic Device Technology Enhancement and Clinical Evaluation at Walter Reed Amputee Center, Project PA9
($10,000) Proton Beam Therapy, Project 968
($3,500) Remote Acoustic Hemostasis, Project 96I
($1,500) Sleep Deprivation Research at Walter Reed Army Medical Center, Project RA1
($12,750) Synchronotron-Based Scanning Research, Project 968
($1,000) Targeted Nano-Therapeutic for Advanced Breast and Prostate Cancer, Project RA2
($11,000) Texas Training and Technology for Trauma and Terrorism (T5), Project 953
($2,100) The Soldier Wound Healing Project, Project PA4
($1,000) Therapeutic Vaccines for Biological Threat, Project RA3
($1,000) Tissue Engineering and Wound Healing Research, Project PA4
($3,000) Tissue Replacement and Repair for Battlefield Injuries, Project 863
($2,000) Transportable Pathogen Reduction and Blood Safety System, Project RA4
($4,250) Versa HSDI, Project RA6

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)

February 2004

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
2 - Applied Research	**0602787A - MEDICAL TECHNOLOGY**	**869**

COST (In Thousands)	FY 2003 Actual	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate
869 T-MED/ADVANCED TECHNOLOGY	3105	3356	3378	3415	3512	3574	3641

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. 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. The cited work is consistent with Strategic Planning Guidance, the Army Science and Technology Master Plan, the Army Modernization Plan, and the Defense Technology Area Plan. 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 2003	FY 2004	FY 2005
Warfighter Physiological Status Monitoring - In FY03, designed prototype handheld Personal Digital Assistant-based physiological monitor for the medic, and provided final sensor specifications and physiological data management algorithms for monitoring heart rate and breathing, wound detection, heat stress, movement, and sleep. In FY04, select sensors for heat stress load and current sleep history, and integrate with Ballistic Injury Detection System and Life Signs Detection System. In FY05, will demonstrate ability to noninvasively monitor alertness in real time in operational settings, measure blood pressure, and incorporate into remote triage algorithm for Future Force Warrior Medic.	3105	3256	3378
Small Business Innovative Research/Small Business Technology Transfer Programs	0	100	0
Totals	3105	3356	3378

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)

February 2004

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

COST (In Thousands)	FY 2003 Actual	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate
870 DOD MED DEF AG INF DIS	26760	13838	15676	16366	16042	15983	16384

A. Mission Description and Budget Item Justification: This project researches and investigates medical countermeasures to naturally occurring infectious diseases potentially affecting the "Medical" technology area of the Future Force. Infectious diseases 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, the bacterial diseases responsible for diarrhea (i.e., caused by Shigella, enterotoxigenic Escherichia coli (ETEC), and Campylobacter), and viral diseases (i.e., dengue fever and hantavirus). The program also develops improved materiel for control of arthropod (insects, ticks, etc.) disease vectors 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 (gene-based) DNA 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. The cited work is consistent with Strategic Planning Guidance, the Army Science and Technology Master Plan, the Army Modernization Plan, and the Defense Technology Area Plan. Work in this project is performed by the Walter Reed Army Institute of Research (WRAIR), 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 (NMRC), Silver Spring, MD and its overseas laboratories. This project contains no duplication with any effort within the Military Departments.

Accomplishments/Planned Program	FY 2003	FY 2004	FY 2005
Malaria Vaccines - In FY03, evaluated candidate DNA and protein malaria vaccines as a part of a multicomponent vaccine; completed preclinical testing of an improved liver-stage malaria vaccine. FY04, produce malaria parasites for use in clinical challenge studies and test development; generate protein and virus-based vaccines; conduct safety and protection studies. FY05, will test DNA and protein vaccine candidates in preclinical trials for inclusion into multicomponent malaria vaccine.	6696	2683	3326

Accomplishments/Planned Program (continued)	FY 2003	FY 2004	FY 2005
Antidiarrheal Vaccines - In FY03, constructed an improved Shigella flexneri candidate vaccine; conducted preclinical studies of ETEC and Campylobacter vaccines; and produced clinical-grade lots of candidate vaccines for testing. In FY04, refine surrogate assays to measure protection by vaccines and develop better animal models for assessing vaccines. Conduct preclinical testing of candidate antidiarrheal vaccines to support Investigational New Drug (IND) applications to the U.S. Food and Drug Administration (FDA). In FY05, will continue clinical testing of candidate vaccines. Will establish an animal model for use in preclinical testing of ETEC vaccines.	8987	2447	3551
Insect Control - In FY03, selected two new insect repellent candidates to potentially replace DEET; continued field study of the dengue vector control system to demonstrate effectiveness in different environments. In FY04, perform final evaluation of selected repellent with human volunteers, compare effectiveness in human trials to other available repellents, and transition to development a new non-DEET repellent. In FY05, will complete testing of a dengue vector control system and transition to development.	2120	920	590
Scrub Typhus Vaccine and Infectious Disease Diagnostics - In FY03, tested a single-strain scrub typhus vaccine in mouse model and established a monkey model to demonstrate vaccine safety and protection. FY04, complete construction of a multistrain vaccine and test safety and protection in animal studies; identify infectious disease diagnostic components compatible for use in a joint services biological agent identification and diagnostic system. In FY05, will start preclinical testing of scrub typhus vaccine to justify FDA Phase 1 clinical trials of candidate vaccine; will develop approaches to supplement infectious disease diagnostics not compatible with joint services diagnostic system.	1699	1385	1677
Vaccines against Dengue Fever, Meningitis and Hemorrhagic Fevers - In FY03, prepared and evaluated dengue vaccines for FDA-approved clinical trials; made progress on genetic engineering of three group B meningitis strains for use in vaccine production; prepared for Phase 1 clinical trials of Hemorrhagic Fever with Renal Syndrome (HFRS) vaccine. In FY04, select the most promising new dengue vaccines for clinical trials and improve as needed; perform preclinical testing of a new component of a multistrain meningitis vaccine. In FY05, will complete construction of the second vaccine component to provide complete protection against HFRS; will submit IND application to test new component for an improved meningitis vaccine; will conduct preclinical testing of improved dengue vaccines.	4323	2036	2020

Accomplishments/Planned Program (continued)	FY 2003	FY 2004	FY 2005
Malaria Drug Candidates - In FY03, conducted preclinical studies of new drug candidates to prevent malaria; completed required preclinical toxicology testing of a new drug to treat severe malaria; prepared IND application for clinical testing; developed animal models that better predict human safety; continued to test new classes of drugs for antimalarial activity. In FY04, select best drug candidates in development pipeline for preclinical and clinical studies using a systematic, streamlined approach for evaluation and optimization of new chemical entities. In FY05, will continue to identify and test new lead compounds identified in discovery via target-directed functional screens coupled with rational drug design technologies; will perform toxicological studies of new drug candidates.	2935	4367	4512
Totals	26760	13838	15676

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)

February 2004

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

COST (In Thousands)		FY 2003 Actual	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate
873	HIV EXPLORATORY RSCH	0	10881	10819	11270	11512	11475	11433

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 by the U.S. Army Medical Research and Materiel Command (USAMRMC) 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. The cited work is consistent with Strategic Planning Guidance, the Army Science and Technology Master Plan, the Army Modernization Plan, and the Defense Technology Area Plan. Work in this project is performed by the Walter Reed Army Institute of Research (WRAIR), Silver Spring, MD and its overseas laboratories; and the Naval Medical Research Center (NMRC), Silver Spring, MD and its overseas laboratories. Most work is conducted under a cooperative agreement with the Henry M. Jackson Foundation (HMJF), Rockville, MD. This project contains no duplication with any effort within the Military Departments.

Accomplishments/Planned Program	FY 2003	FY 2004	FY 2005
HIV - In FY03, HIV program transferred to the National Institutes of Health. Program returned to USAMRMC in FY04. In FY 04, construct additional candidate vaccines that induce broader anti-HIV immune responses against various HIV subtypes found outside the United States and important in military deployments. Continue genetic analysis of HIV subtypes isolated in Africa for integration into vaccine candidates for this region. Develop HIV vaccine study populations for future field trials in Kenya and Uganda. Support global surveillance of HIV-1 to target international HIV-1 vaccine development and inform the U.S. military of the HIV threat in areas of potential troop deployment through the existing network of overseas collaborators, with special attention to surveillance in Eastern Europe and countries of the former Soviet Union. Maintain U.S. Military Clinical Intervention Network operated through Military Medical Treatment Facilities to study the frequency and impact of HIV/AIDS in/on military populations, especially when consequent to troop deployments. Identify cost-effective drugs and care strategies to control HIV infection and transmission in military populations. FY05, will 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 expand to Tanzania, and Cameroon. Maintain global surveillance network for HIV-1 infections. Maintain U.S. Military Clinical Intervention Network operated through Military Treatment Facilities to study the frequency and impact of HIV/AIDS in/on military populations. Maintain technical watch for new antiretroviral drugs.	0	10576	10819
Small Business Innovative Research/Small Business Technology Transfer Programs	0	305	0
Totals	0	10881	10819

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)

February 2004

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
2 - Applied Research	**0602787A - MEDICAL TECHNOLOGY**	**874**

COST (In Thousands)		FY 2003 Actual	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate
874	CBT CASUALTY CARE TECH	8487	8668	8469	16051	13838	11914	9148

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. 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 include blood products; resuscitation fluids; drugs and devices to control severe bleeding; methods to minimize, repair, and prevent injury; and diagnostic and predictive indicators for remote triage and computerized, autonomous patient care. Additional goals are to reduce evacuations due to dental disease and reduce the medical footprint on the battlefield. The cited work is consistent with Strategic Planning Guidance, the Army Science and Technology Master Plan, the Army Modernization Plan, and the Defense Technology Area Plan. Work in this project is performed by the U.S. Army Institute of Surgical Research, Fort Sam Houston, TX, and the Walter Reed Army Institute of Research, Silver Spring, MD.

Accomplishments/Planned Program	FY 2003	FY 2004	FY 2005
Freeze Dried Plasma - In FY03, demonstrated 1-year stability of freeze-dried plasma to characterize its usefulness as a clinical product; completed animal studies comparing the effect of low-volume resuscitation on survival after severe blood loss. In FY04, conduct manufacturing and testing of pilot lots of freeze-dried plasma and novel storage containers; submit investigational new drug (IND) application for freeze-dried plasma to the U.S. Food and Drug Administration (FDA); and conduct animal testing of freeze-dried plasma. In FY05, will prepare for clinical testing of freeze-dried plasma, complete studies of low-volume fluid resuscitation, and identify new candidate chemical additives for resuscitation fluids to improve outcome of resuscitated casualties; 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. The simulator will require no external support equipment other than a power connection.	3137	3000	2965
Blood Clotting Agents - In FY03, completed studies to determine optimum dosage of blood clotting factor VIIa, and selected best dose for subsequent studies to control severe bleeding; demonstrated that the combination of factor VIIa with other hemostatic drugs did not enhance clotting; and established a brain injury animal model for studying effects of new blood clotting agents on brain injury. In FY04, initiate animal studies of candidate drugs to evaluate potential to restore blood clotting in casualties who have abnormal clotting to increase survival of battlefield casualties. In FY05, will complete animal studies of candidate drugs to evaluate their potential to restore blood clotting in casualties who have abnormal clotting and submit IND application to FDA for candidate drug to restore blood-clotting function.	1727	1542	1462

Accomplishments/Planned Program (continued)	FY 2003	FY 2004	FY 2005
Brain, Tissue, and Bone Injury - In FY03, developed a large-animal model of fatal extremity injury for study of methods to manage tissue and bone injuries caused by land mines and shrapnel weapons for study of new wound management methods. Initiated an animal study of a candidate bone replacement material; demonstrated the effectiveness of two drugs to reduce surrounding tissue injury after a stroke; identified two licensed drugs with potential to treat silent brain seizures associated with brain injury; started a clinical trial of a candidate spray wound dressing; and developed consensus guidelines for tourniquet use on the battlefield. In FY04, conduct initial studies of an antimicrobial wound-cleaning device; conduct initial studies of lightweight materials and splints for fracture stabilization, and evaluate candidate neuroprotective drugs in cell culture and in an animal model of brain injury. In FY05, will down-select and conduct clinical testing of an advanced prototype wound protective barrier device; will submit an investigational device exemption application for a prototype wound protective barrier device; and will continue studies in animal models to determine the effectiveness of candidate drugs to mitigate brain injury after head trauma.	1645	1831	2122
Dental Disease and Soldier Status Monitoring - In FY03, started a Phase 1 animal toxicity study of a candidate chemical additive for meals-ready-to-eat (MREs) for prevention of dental disease; demonstrated stability of freeze-dried plasma at room temperature for up to 1 year. In FY04, conduct a Phase 2 animal toxicity study of a candidate chemical additive for MREs; adapt handheld microimpulse radar (MIR) system for heart rate and respiration detection into a wearable system. In FY05, will conduct a Phase 3 animal toxicity study of a candidate chemical additive for MREs for prevention of dental disease; will transition handheld MIR for heart rate monitoring to System Development and Demonstration.	1978	2203	1920
Small Business Innovative Research/Small Business Technology Transfer Programs	0	92	0
Totals	8487	8668	8469

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)

February 2004

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

COST (In Thousands)		FY 2003 Actual	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate
878	HLTH HAZ MIL MATERIEL	11038	11521	12116	12140	12276	12404	12637

A. Mission Description and Budget Item Justification: This project supports "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. 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, the Army Modernization Plan, and the Defense Technology Area Plan. 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 2003	FY 2004	FY 2005
Laser Eye Hazard Protection - In FY03, evaluated drugs to minimize secondary nerve injury from battlefield lasers and refined exposure limits to minimize laser eye injury hazards. In FY04, test genomic/polemic (study of protein expression and function) derived laser eye injury treatments in non-human primates. In FY05, will develop laser eye injury triage, treatment, and protection applications.	3432	3421	4134
Restraint Technologies - In FY03, defined injury thresholds for dynamic responses in restraint systems for Army ground and air vehicles. In FY04, provide validated repeated jolt guidelines and proposed standards for safe operations of tactical ground vehicles for use in the Health Hazard Assessment program. Provide performance standards for effective military restraint systems. In FY05, will translate validated restraint and jolt standards into a biomedical valid virtual prototyping model.	1249	1358	984

Accomplishments/Planned Program (continued)	FY 2003	FY 2004	FY 2005
Body Armor Assessment - In FY03, fully characterized forces behind soft and hard body armor due to blunt force trauma, developed final animal and preliminary human mathematical models, began animal injury studies, and developed prototype body armor test device for body armor developers. In FY04, complete animal injury studies, validate animal model with injury data, and complete human model. In FY05, will complete behind armor blunt trauma injury prediction software for body armor developers and subsequent transition to Natick Soldier Center.	3630	3814	3720
Environmental Health Biomonitor - In FY03, designed two tests to assess the reproductive health effects of militarily relevant chemicals and mixtures. In FY04, complete integration of graphic user interface with the portable aquatic biomonitor for biologically based toxicity sampling. In FY05, will evaluate and select biomonitor components for the environmental sentinel biomonitor for rapid identification of acute toxic hazards in water.	2727	2697	3278
Small Business Innovative Research/Small Business Technology Transfer Programs	0	231	0
Totals	11038	11521	12116

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)

February 2004

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

COST (In Thousands)		FY 2003 Actual	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate
879	MED FACT ENH SOLD EFF	8515	8740	10419	10540	10552	10588	10777

A. Mission Description and Budget Item Justification: This project supports "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 multi stressor 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, the Army Modernization Plan, and the Defense Technology Area Plan. 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 2003	FY 2004	FY 2005
Neural Network Model - In FY03, established neural network model, tested dehydration component of model, and validated terrain coefficients in the model. In FY04, complete the model of cold, heat, and altitude stress to predict individual and unit-level performance outcomes based on environmental and operational variables. In FY05, will integrate temperature regulation and hybrid neural network models into the SCENARIO model.	2030	2310	2739
Fatigue Intervention - In FY03, provided guidance on using caffeine, modafinil, and amphetamines to fight fatigue. In FY04, establish a sleep model that predicts the effects of stimulants and naps on performance. In FY05, will demonstrate a comprehensive fatigue and performance model for group predictions of soldier performance in continuous operations.	2552	1679	2298
Psychiatric Casualty Prevention - In FY03, developed a tool to assess cognitive function in the field and developed an Army-wide suicide surveillance system. In FY04, identify factors that predict high rates of mental disorders and define the association of mental health with readiness. In FY05, will propose effective methods for psychological health screening in deployed troops, and will analyze health care databases to assess health patterns related to attrition.	2187	2448	3052

Accomplishments/Planned Program (continued)	FY 2003	FY 2004	FY 2005
Visual Performance - In FY03, established visual performance criteria for the integration of flat panel displays into helmet-mounted devices. In FY04, determine the effect of eyesight correction on visual performance with electro-optical devices and complete visual detection model to include complex targets and backgrounds. In FY05, will conduct comprehensive clinical and laboratory studies and assess flight performance in aviators who have refractive surgery. The results will serve as the basis for recommendations on Army aviator accession and retention standards.	1746	2222	2330
Small Business Innovative Research/Small Business Technology Transfer Programs	0	81	0
Totals	8515	8740	10419