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

June 2001

BUDGET ACTIVITY
2 - APPLIED RESEARCH

PE NUMBER AND TITLE
0602787A - Medical Technology

	COST (In Thousands)	FY 2000 Actual	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	Cost to Complete	Total Cost
	Total Program Element (PE) Cost	169967	111696	82494	0	0	0	0	0	0	0
838	NEUROTOXIN EXPOSURE TRTMT	9547	0	0	0	0	0	0	0	0	0
841	COMPUTER-ASST MINIMALLY INVASIVE SURGERY	9547	13872	5000	0	0	0	0	0	0	0
845	BONE DISEASE RESEARCH PROGRAM	6231	5945	0	0	0	0	0	0	0	0
863	BTLFLD SURGICAL REPLAC	2386	0	0	0	0	0	0	0	0	0
869	T-MED/ADVANCED TECHNOLOGY	5073	4426	4500	0	0	0	0	0	0	0
870	DOD MED DEF AG INF DIS	23250	24612	25684	0	0	0	0	0	0	0
872	NEUROFIBROMATOSIS RSCH	14320	0	0	0	0	0	0	0	0	0
873	HIV EXPLORATORY RSCH	12212	11473	11069	0	0	0	0	0	0	0
874	CBT CASUALTY CARE TECH	8384	10212	9086	0	0	0	0	0	0	0
878	HLTH HAZ MIL MATERIEL	9072	10545	11408	0	0	0	0	0	0	0
879	MED FACT ENH SOLD EFF	7892	8361	8747	0	0	0	0	0	0	0
921	OVARIAN CANCER RESEARCH	11456	0	0	0	0	0	0	0	0	0
952	MUSCULOSKELETAL INJURIES	5729	0	0	0	0	0	0	0	0	0
953	DISASTER RELIEF & EMERGENCY MEDICAL SVC (DREAMS)	9547	0	0	0	0	0	0	0	0	0
962	POLYNITROXYLATED HEMOGLOBIN	1909	0	0	0	0	0	0	0	0	0
963	NATIONAL MEDICAL TESTBED	14320	0	0	0	0	0	0	0	0	0
964	INFORMATICS-BASED MED. EMERG DECIS TOOLS (IMED)	4295	5945	0	0	0	0	0	0	0	0
965	EYE RESEARCH	1909	0	0	0	0	0	0	0	0	0
966	BLOOD RESEARCH	5251	0	0	0	0	0	0	0	0	0
967	DYE TARGETED LASER FUSION	2864	3963	0	0	0	0	0	0	0	0
968	SYNCH BASED HI ENERGY RADIATION BEAM CANCER DETECT	4773	0	0	0	0	0	0	0	0	0
96A	EMERGENCY HYPOTHERMIA	0	2972	0	0	0	0	0	0	0	0
96B	REAL TIME HEART RATE VARIABILITY TECHNOLOGY	0	2477	0	0	0	0	0	0	0	0

977	EMERGING INFECTIOUS DISEASES	0	6893	7000	0	0	0	0	0	0	0

A. Mission Description and Budget Item Justification:

PLEASE NOTE: This administration has not addressed FY2003-2007 requirements. All FY 2003-2007 budget estimates included in this book are notional only and subject to change.

This program element supports focused research for healthy, medically protected soldiers, and funds research consistent with the "Medical", "Survivability", and "Future Warrior" technology areas of the Objective Force. The primary goal of medical research and development is to sustain medical technology superiority to improve the protection and survivability of U.S. forces on conventional battlefields as well as in potential areas of low intensity conflict and military operations short of war. This program element funds applied research in Department of Defense (DOD) medical protection against naturally occurring diseases of military importance and combat dentistry, as well as applied research for Department of Army care of combat casualties, health hazard assessment of military materiel, and medical factors enhancing soldier effectiveness. This program element is the core DOD technology base to develop methods and materials for infectious disease prevention and treatment including vaccines, prophylactic and therapeutic drugs, insect repellents, and methods of diagnosis and identification of naturally occurring infectious diseases; prevention and treatment of combat maxillofacial (face and neck) injuries, and essential dental treatment on the battlefield; combat casualty care of trauma and burns due to weapons, organ system survival, shock resulting from blood loss and infection, blood preservation, and potential blood substitutes for battlefield care; assessment of the health hazards of military materiel, and the sustainment or enhancement of soldier performance. The cited work is consistent with the Army Science and Technology Master Plan (ASTMP), the Army Modernization Plan and Project Reliance. The program element contains no duplication with any effort within the Military Departments. This program is managed by the U.S. Army Medical Research and Materiel Command. This program supports the Objective Force transition path of the Transformation Campaign Plan (TCP).

B. Program Change Summary	FY 2000	FY 2001	FY 2002	FY 2003
Previous President's Budget (FY2001 PB)	174199	75729	70269	0
Appropriated Value	176636	112729	0	
Adjustments to Appropriated Value	0	0	0	
a. Congressional General Reductions	0	0	0	
b. SBIR / STTR	-4247	0	0	
c. Omnibus or Other Above Threshold Reductions	-652	0	0	
d. Below Threshold Reprogramming	15	0	0	
e. Rescissions	-1785	-1033	0	
Adjustments to Budget Years Since FY2001 PB	0	0	12225	
Current Budget Submit (FY 2002/2003 PB)	169967	111696	82494	0

Change Summary Explanation: Funding - FY 2001 includes the following Congressional adds. The objective of these one year adds is to develop and complete the following:
Project 841, Computer-Assisted Minimally Invasive Surgery (+12000)- By Congressional direction this program funds the development of computer-based surgical devices.
Project 841, Minimally Invasive Research for Brain and Spine (+2000)- By Congressional direction, this is to fund continuing research into the development of minimally invasive surgical procedures for the brain, spinal cord and spine.
Project 967, Dye Targeted Laser Fusion (+4000)- These funds are for research into hemorrhage control by sealing tissues using medical lasers.

Project 96A, Emergency Hypothermia (+3000)- By Congressional direction, this program funds research into emergency hypothermia treatments.
Project 964, IMED Tools (+6000)- By Congressional direction, these funds are only for the IMED Tools Project, which addresses the limitations of medical care in the face of a mobile, digitized, high-threat military environment.
Project 845, Osteoporosis and Bone Disease Research Program (+6000)- Study bone physiology leading strategies to improve bone health of young men and women, reducing the incidence of stress fracture during physically intensive training.
Project 96B, Real-Time Heart Rate Variability Technology (+2500)- By Congressional direction, this is to conduct research of real-time heart rate variability technology to enhance trauma victim survivability.

FY 2002 funding increased to support the following:
Project 841- Computer-Asst Minimally Invasive Surgery (+5000)
Project 977- Emerging Infectious Diseases (+7000)

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

June 2001

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
2 - APPLIED RESEARCH	**0602787A - Medical Technology**	**841**

COST (In Thousands)		FY 2000 Actual	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	Cost to Complete	Total Cost
841	COMPUTER-ASST MINIMALLY INVASIVE SURGERY	9547	13872	5000	0	0	0	0	0	0	0

A. Mission Description and Budget Item Justification: By Congressional direction, this program supports continuation of development of sophisticated computer-based surgical devices. This program will improve technologies developed under the program, including, but not limited to, integration of an intraoperative ultrasound imaging device, a small fiber endoscope, and application of an intraoperative magnetic resonance imaging device.

FY 2000 Accomplishments

- 9547 Continued development of minimally invasive surgical technologies in five key Clinical Focus Areas: Cardiovascular disease, Cancer, Stroke, Trauma and Critical Care, and New Initiatives at Massachusetts General Hospital's Center for Innovative Minimally Invasive Therapy (CIMIT).

Total 9547

FY 2001 Planned Program

- 13460 - Continue development of minimally invasive surgical technologies at the Center for Innovative Minimally Invasive Therapy.
  - Continue Minimally Invasive Surgery research at Georgetown University's Department of Radiology.
- 412 Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs.

Total 13872

FY 2002 Planned Program

•	5000	Continue development of minimally invasive surgical technologies at the Center for Innovative Minimally Invasive Therapy.
Total	5000	

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

June 2001

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
2 - APPLIED RESEARCH	**0602787A - Medical Technology**	**869**

COST (In Thousands)		FY 2000 Actual	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	Cost to Complete	Total Cost
869	T-MED/ADVANCED TECHNOLOGY	5073	4426	4500	0	0	0	0	0	0	0

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 Warrior Objective 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. Intramural research under this project is conducted at the following U.S. Army Medical Research and Materiel Command laboratories: the Aeromedical Research Laboratory, the Research Institute of Environmental Medicine, the Institute of Surgical Research, and the Walter Reed Army Institute of Research and its overseas laboratories. This program supports the Objective Force transition path of the Transformation Campaign Plan (TCP).

FY 2000 Accomplishments

- 2094 - Conducted applied research on a microimpulse radar unit for noninvasive cardiac output monitoring, and an acoustic method to detect tension pneumothoraces (collapsed lung) to measure the physiologic state of soldiers noninvasively and help battlefield medics diagnose and treat wounded soldiers. The cardiac output monitor demonstrated decreased cardiac output due to blood loss (as expected). Pneumothorax detection requires further study to improve reliability.

  - Began investigation into a noninvasive intracranial pressure monitor to assess intracranial pressure in closed head trauma and started the design of a high frequency focused ultrasound device that will stop bleeding in organs.

- 2491 - Conducted applied research to construct a prototype for first-generation Warfighter Physiological Status Monitoring (WPSM) of soldier status and conducted evaluations on soldiers undergoing exercises at the Dismounted Battlespace Battle Lab.

  - Tested the ability of the Land Warrior's Dead Reckoning Module to detect projectile impacts on a soldier's body and to collect mission-specific physiological data from soldiers with the goal of helping the medic assess the soldier's health status.

- 488 - Conducted applied research on the Joint Medical Operations-Telemedicine Advanced Concept Technology Demonstration (ACTD) by developing and evaluating Theater Telemedicine Team operational concepts to improve healthcare delivery in the battle zone.

Total 5073

FY 2001 Planned Program

•	1896	- Conduct applied research to measure the physiologic state of soldiers by evaluating prototype microwave and acoustic devices for the detection of pneumothorax (collapsed lung), hemothorax (bleeding in chest), and subdural hematoma (head trauma) in large-animal models of these conditions. Evaluate wide band and narrow band radar approaches to heart rate and respiratory rate monitoring through clothing and mission-oriented protective posture (MOPP) gear.
		- Assess systems to identify a wounding event based on characteristic acoustic signatures produced by projectiles impacting the body. Investigate methods to establish a database of human physiological responses collected immediately after severe trauma that will be the basis of algorithms to help combat medics diagnose wounded soldiers.
•	2399	- Conduct applied research to continue support for the WPSM to assess and predict individual warfighter status. Utilize the WPSM database and data acquisition and management capabilities, to support the formulation and testing of modeling strategies.
		- Generate knowledge management system to reduce information from WPSM and predictive performance and health risk models to only that which is essential to commanders. This provides the basis of a sensor fusion and situational interpretation of soldier physiological data.
•	131	Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs.
Total	4426	

FY 2002 Planned Program

•	1978	- Conduct applied research to measure the physiologic state of soldiers by testing and refining a prototype microwave or acoustic device to detect pneumothorax, hemothorax, and subdural hematoma through clothing and MOPP gear. Construct a prototype device based on the principles of pulse plethysmography (measuring variations in the size of an organ or body part on the basis of the amount of blood passing through or present in the part) and pulse wave transmission for the measurement of systolic, diastolic, and mean blood pressures.
		- Develop and test a prototype system to detect a wounding event by identifying characteristic acoustic signatures of projectiles impacting the body. Establish a database of human physiological responses collected immediately after severe trauma.
•	2522	- Conduct applied research to continue support for WPSM to assess warfighter health status. Develop knowledge management system to reduce information from WPSM and predictive and health risk models to only that which is essential to warfighters.
		- Utilize WPSM database, and data acquisition and management capability, to support the development and testing of model strategies to predict individual warfighter status, as a component of technologies applied to the "Future Warrior" technology area. This effort will improve near real-time assessment of physiological performance, optimizing utilization of the individual warfighter.
Total	4500	

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

June 2001

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
2 - APPLIED RESEARCH	**0602787A - Medical Technology**	**870**

COST (In Thousands)	FY 2000 Actual	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	Cost to Complete	Total Cost
870 DOD MED DEF AG INF DIS	23250	24612	25684	0	0	0	0	0	0	0

A. Mission Description and Budget Item Justification: This project supports development of medical countermeasures to naturally occurring infectious diseases consistent with the "Medical" technology area of the Objective Force. Infectious diseases pose a significant threat to 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. Intramural research under this project is conducted at the U.S. Army Medical Research and Materiel Command's Medical Research Institute of Infectious Diseases, the Walter Reed Army Institute of Research and its overseas laboratories, and the Naval Medical Research Center and its overseas laboratories. Major contractors are the Israeli Defense Force Medical Corps, Israel; ProMed Trading, SA, Panama; Nanogen Inc., San Diego, CA; and the Research Triangle Institute, Research Triangle Park, NC. This program supports the Objective Force transition path of the Transformation Campaign Plan (TCP).

FY 2000 Accomplishments

- 7921 Refined screening methods for evaluating anti-malaria drugs, new methods for measuring immune responses in malaria infection, and new assays for characterizing malaria parasites during development of field trial sites.

  - Conducted multiple animal tests of candidate malaria vaccines, targeting all stages of parasite's life cycle. Explored efficacy of various dosing schedules for administering multiple candidate vaccines to test animals.

  - Continued screening of candidate anti-malaria drugs, and evaluation against malaria parasites collected in Thailand, Kenya, Brazil, Peru, Indonesia, and Egypt.

- 4244 Modified candidate vaccines against major causes of bacterial diarrhea (three organisms), evaluated them against specimens from Thailand, China, and Vietnam. Prepared vaccine pilot lots in accordance with FDA requirements, for later animal and human testing.

- 5698 Continued co-development (with biological defense program) of rapid infectious organism test battery for field use. Advanced understanding of hepatitis E infection process as step toward vaccine development. Animal tested candidate scrub typhus vaccine. Completed second stage of Phase I human test of meningitis B vaccine. Further evaluated candidate compounds to replace current military insect repellant.

- 5387 Elaborated immune mechanisms critical to development of effective dengue vaccine. Developed new screening methods to improve dengue vaccine safety testing. Explored immune factors in severe dengue fever and dengue hemorrhagic fever.

Total 23250

FY 2001 Planned Program

•	11557	- Determine human immune response factors that protect against malaria, modify candidate vaccines to enhance immunogenicity, and conduct monkey-safety and immunogenicity trials on selected vaccines for both falciparum and vivax malaria species. - Determine the three-dimensional structure of vital malaria enzymes to identify drugs that can disrupt the enzyme's function. Determine through genetic manipulation the function of specific malaria proteins to identify the best drug targets. - Evaluate newer, more potent candidate drugs for prophylaxis and treatment of multi-drug resistant strains of malaria and test in monkeys.
•	7072	- Study epidemiology of Campylobacter to determine the most prevalent Campylobacter serotypes to guide vaccine development and conduct clinical study to determine if Campylobacter antigens are involved in the occurrence of Guillain-Barre Syndrome (GBS) in order to ensure a safe vaccine design. - Design and test in animal models vaccine candidates for Shigella and ETEC, including a vaccine expressing proteins from both, and a Campylobacter vaccine given with and without an immune booster.
•	4124	-Conduct research on the components of diagnostic tests to be applied to a common diagnostic device for biological defense and infectious disease threats, on vaccines to prevent meningitis caused by Group B meningococcus, and on control of insect vectors of disease. - Characterize a genetically modified candidate Group B meningitis vaccine to verify that it exhibits reduced toxicity and high immunogenicity, and evaluate the effect of immune boosters on efficacy. - Conduct testing of an insect repellent to replace the current military repellent, DEET, to ensure that it meets Environmental Protection Agency safety requirements and that it repels chiggers.
•	1377	- Conduct research on vaccines to prevent viral diseases capable of interrupting combat operations by constructing improved, second generation live-attenuated vaccines for dengue. Evaluate the protective efficacy of an orally administered DNA vaccine against dengue 2 in mice. Improve DNA vaccines delivered by gene-gun and test in animals.
•	482	Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs.
Total	24612	

FY 2002 Planned Program

- 11299 - Complete preclinical testing of vivax malaria vaccine candidates and conduct animal studies to evaluate safety and immunogenicity of a candidate falciparum malaria vaccine.

  - Validate a DNA-based test for measuring malaria parasites in blood and screen candidate antimalarial drugs to determine the safety profile, dose levels, and toxicity in animal models to meet FDA requirements for human studies.

- 5384 - Complete preclinical testing of Shigella dysenteriae vaccine candidate as required by the FDA and conduct animal-safety and immunogenicity studies of ETEC and Campylobacter candidate vaccines.

- 3061 - Modify the candidate scrub typhus vaccine to make it more broadly protective. Design improved vaccine candidates to prevent acute respiratory disease caused by adenovirus in military trainees.

  - Evaluate candidate insect repellent compounds to replace DEET and design final components of a system to provide identification and control of the mosquitoes that transmit dengue fever.

  - Validate DNA-based tests for the identification of militarily important pathogens from Southeast Asia and incorporate these tests onto the Department of Defense's Common Diagnostic System Platform. Complete diagnostic test validation of the nucleic acid-based tests for identification of Shigella flexneri, malaria, dengue, and hantavirus.

- 5940 - Complete preclinical testing of a candidate hantavirus DNA vaccine in compliance with FDA standards. Screen antiviral compounds for activity against hantaviruses to support improving drug therapy.

Total 25684

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

June 2001

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
2 - APPLIED RESEARCH	**0602787A - Medical Technology**	**873**

COST (In Thousands)	FY 2000 Actual	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	Cost to Complete	Total Cost
873 HIV EXPLORATORY RSCH	12212	11473	11069	0	0	0	0	0	0	0

A. Mission Description and Budget Item Justification: This project supports the "Medical" technology area of the Objective Force by conducting applied research of improved diagnostics, epidemiology, candidate immunogens, promising drugs and behavioral modification for prevention and treatment of human immunodeficiency virus (HIV). Main efforts include developing experimental models of disease, preparation of new vaccine candidates, improved diagnosis of disease, and risk assessment. Intramural research under this project is conducted at the U.S. Army Medical Research and Materiel Command's Walter Reed Army Institute of Research and its overseas laboratories, and the Naval Medical Research Center and its overseas laboratories. Major contractors are the Henry M. Jackson Foundation, Rockville MD; McKesson Bioservices, Rockville MD; SRA Technologies, Falls Church VA; Harvard University, Cambridge MA; and Kenya Medical Research Institute, Kenya. This program supports the Objective Force transition path of the Transformation Campaign Plan (TCP).

FY 2000 Accomplishments

- 12212 - Continued efforts to characterize various strains of HIV virus from samples collected worldwide. Further characterized components of HIV virus that may induce protective response leading to vaccine development.

  - Conducted pre-clinical studies of vaccine candidates based on variety of technologies and elucidated cellular mechanisms of immune cells when confronted with HIV virus.

  - Continued field surveys of high-incidence disease areas (Uganda, Kenya, Thailand) in preparation for human clinical trials.

Total 12212

FY 2001 Planned Program

- 11142 - Conduct specialized laboratory studies of HIV virus and human host cell interactions, including virus entry into human cells, targeting of HIV vaccines to human immune cells, binding of candidate vaccines to human immune cells, and conduct studies of HIV virus and immune system factors that are associated with immunity.

  - Develop manufacturing processes and produce pilot lots of vaccine (VEE replicon particles, a recombinant anthrax-vectored vaccine and a mucosally administered vaccine). Also conduct sample processing and storage activities in support of vaccine testing and development.

FY 2001 Planned Program (Continued)

- Conduct multi-service, multi-center clinical studies of the effectiveness of testing for HIV drug resistance for the management of HIV infection in military service members and other military health-care beneficiaries.

- Conduct studies of candidate vaccines (an orally administered S. flexneri-vectored vaccine and a subtype E naked-DNA vaccine) in animal models to determine safety and efficacy for producing an immune response before studies are begun in humans.

• 331 Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs.

Total 11473

FY 2002 Planned Program

• 11069 - Conduct specialized laboratory studies of HIV virus and human host cell interactions, including virus entry into human cells, targeting of HIV vaccines to human immune cells, binding of candidate vaccines to human immune cells; and conduct studies of HIV virus and immune system factors that are associated with immunity.

- Conduct studies of candidate vaccines in animal models to determine safety and efficacy for producing an immune response before studies are begun in humans.

- Develop manufacturing processes and produce pilot lots of vaccine (DNA vaccines for subtypes D&E and Modified Vaccinia Ankara (MVA) vaccine for subtype D).

Total 11069

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

June 2001

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
2 - APPLIED RESEARCH	**0602787A - Medical Technology**	**874**

COST (In Thousands)		FY 2000 Actual	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	Cost to Complete	Total Cost
874	CBT CASUALTY CARE TECH	8384	10212	9086	0	0	0	0	0	0	0

A. Mission Description and Budget Item Justification: This project addresses investigation of the treatments for weapons-induced trauma and shock due to blood loss on the battlefield in order to provide healthy, medically protected soldiers as outlined in the "Medical" technology area of the Objective Force. This project funds the core technology base to develop concepts, techniques, and material for the treatment and return-to-duty of soldiers wounded in combat and to support low-intensity combat as well as military operations other than war. It also funds technologies for resuscitation fluid and methods to prolong the shelf life of blood products. Intramural research under this project is conducted at the U.S. Army Medical Research and Materiel Command's Institute of Surgical Research, and the Walter Reed Army Institute of Research and its overseas laboratories. A major contractor is the University of Washington, Seattle, WA. This program supports the Objective Force transition path of the Transformation Campaign Plan (TCP).

FY 2000 Accomplishments

- 1621 - Conducted applied research to reduce the logistical burden of blood products on the battlefield by studies to develop a liquid red blood cell storage system that increase the current six-week storage time to ten weeks. Began evaluation of techniques for the formulation and assessment of dried plasma products.
- 1518 - Conducted applied research in novel methods of stopping bleeding and limiting blood loss by evaluating the potential use of Food and Drug Administration (FDA)-approved drugs to decrease blood loss after severe liver injury. Assessed the importance of hypothermia as a means of stopping blood loss (coagulopathy) during hemorrhage.
- 2667 - Conducted applied research into low blood pressure resuscitation; determined the arterial pressure at which rebleeding occurs during resuscitation to enhance the resuscitation capabilities for combat medics.

  - Evaluated concentrated resuscitation fluid therapy to reduce battlefield deaths after combined brain trauma and hemorrhage. Identified the effects of hemorrhage on gene expression to find novel ways of preventing shock.

  - Developed nitric oxide inhibitors to prevent injury caused by low blood flow after hemorrhage.

FY 2000 Accomplishments (Continued)

- 878 Conducted applied research on novel methods to minimize, repair, and prevent injuries to soft tissues by examining the neuroprotective efficacy of biologic compounds such as an oxygen-carrying red blood cell substitute and enzyme inhibitors that protect against injury caused by loss of blood, a major cause of death on the battlefield. Studied therapies to reduce the effects of burns and smoke inhalation suffered by soldiers on the battlefield.

- 1700 - Evaluated medical command and control and patient management software capabilities on lightweight telemedicine hardware that enable deployed Joint Forces to supply better patient care as part of the Medical Operations-Telemedicine Advanced Concept Technology Demonstration.

  - Developed and evaluated Theater Telemedicine Team to provide operational support concepts for deployed forces.

Total 8384

FY 2001 Planned Program

- 1202 - Conduct applied research on a freeze-drying process for plasma and evaluate the dangerous inflammatory effects from blood stored for varying periods of time to reduce the logistical burden of blood products on the battlefield.
- 2311 - Conduct applied research in novel methods of stopping bleeding and limiting blood loss by continuing the assessment of FDA-approved drugs for decreasing blood loss following severe injury to prevent battlefield hemorrhage related deaths.

  - Test efficacy of recombinant clotting factor VIIa to stop bleeding from various types of injuries. Construct a prototype high frequency-focused ultrasound device to stop bleeding in organs.
- 2886 - Conduct applied research in new methods of resuscitation by comparing various resuscitation fluids in animal models to control hemorrhage while kept at low blood pressure; compare controlled versus uncontrolled hemorrhage to determine the best animal model to predict the response of humans and examine inflammation in animal models to reduce hemorrhagic shock during resuscitation.

  - Develop a second generation eye oximeter to noninvasively measure if the brain is getting enough oxygen.

  - Evaluate lower body negative pressure as a surrogate model of hemorrhagic shock to allow the gathering of data on humans without having to remove their blood.
- 2105 - Conduct applied research on novel methods to minimize, repair, and prevent injuries to hard and soft tissues to evaluate repair methods using a large-animal model for contaminated bone defects of the extremities.

  - Test the effect of aerosolized indomethacin to reduce the effects of smoke inhalation. Design a delivery system for the nasal application of ketamine to manage trauma-related pain.

  - Evaluate physiologic tolerance levels following traumatic brain injury and a treatment approach to injury-induced edema.

FY 2001 Planned Program (Continued)

- 1500 - This one-year Congressional add will conduct research in methods to purify blood products right on the battlefield. It will fund Emergency Blood Purification for Combat Casualty Care.
- 208 Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs.

Total 10212

FY 2002 Planned Program

- 1020 - Conduct applied research to reduce the logistical burden of blood products on the battlefield by refining the freeze-drying process for plasma to result in efficient and consistent production of a stable freeze-dried product for field application. Complete design and testing of a prototype device to detect infectious diseases such as human immunodeficiency virus (HIV) in blood to make transfusions safer.
- 2789 - Conduct applied research in novel methods of stopping bleeding and limiting blood loss by selecting the most effective FDA-approved drugs for decreasing blood loss following severe liver injury. Complete the examination of the safety and efficacy of recombinant factor VIIa in the treatment of traumatic brain injury and in generalized uncontrolled hemorrhage.

  - Refine the prototype high frequency focused ultrasound device that will stop bleeding in organs.

  - Complete the evaluation of the lower body negative pressure as a surrogate model of hemorrhagic shock.
- 2601 - Conduct applied research in new methods of resuscitation by completing the study of various resuscitation fluids and recommending the best commercial off-the-shelf (COTS) fluid.

  - Examine methods to modify inflammatory processes in animals subjected to severe blood loss to reduce shock and improve survival.

  - Complete the construction of a second-generation eye oximeter to noninvasively measure that the brain is getting enough oxygen.
- 2676 - Conduct applied research on novel methods to minimize, repair, and prevent injuries to hard and soft tissues and complete the evaluation of repair methods on a large-animal model for contaminated bone defects of the extremities.

  - Construct and test a device to measure absolute cerebrospinal fluid pressure after head trauma and thereby reduce deaths due to increased cranial pressure.

  - Conduct animal trials of a molecular biology-based method to reduce mucus secretion in bronchioles after smoke inhalation and thereby lower the death rate.

Total 9086

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

June 2001

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
2 - APPLIED RESEARCH	**0602787A - Medical Technology**	**878**

COST (In Thousands)	FY 2000 Actual	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	Cost to Complete	Total Cost
878 HLTH HAZ MIL MATERIEL	9072	10545	11408	0	0	0	0	0	0	0

A. Mission Description and Budget Item Justification: This supports "Medical" and "Survivability" Objective Force Technology Areas 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; non-ionizing radiation directed energy sources (laser); and environmental stressors (e.g. heat, cold, 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. Intramural research is conducted at the Aeromedical Research Laboratory, the Research Institute of Environmental Medicine, and the Walter Reed Army Institute of Research. Major contracts are with Universal Energy Systems and JAYCOR. Additionally, numerous Cooperative Research and Development Agreements (CRDAs) are held with universities and independent laboratories. This program supports the Objective Force transition path of the Transformation Campaign Plan (TCP).

FY 2000 Accomplishments

- 1126 Characterized damage mechanisms to predict injury thresholds for emerging blue light laser systems (wavelengths equal to 400-500nm) that are being considered in future combat systems.
- 550 Determined range safety standards to prevent dazzling of pilots and vehicle operators from short duration laser flash effects.
- 649 Produced an interim Health Hazard Assessment method and standard for repeated jolt that will be important to guide design of the future combat system so that it does not impair health or performance of the soldier.
- 650 Determined the effect of cockpit airbag system deployment on in-flight injury rates and ability to land an aircraft.
- 933 Created and refined a user-friendly method for the operator to test visual display quality of psychophysical information to determine the display's serviceability in order to insure optimal display quality.
- 1461 Described pathophysiology (damage to body) of combined fire gas inhalation exposure for predictive modeling of combined gas injury and incapacitation, which will lead to the development of effective countermeasures to toxic fumes.

FY 2000 Accomplishments (Continued)

- 1269 Established a research program to develop operational guidelines and design criteria for mass properties of head-supported devices based on warfighter injury risk and performance degradation, which will reduce acute and chronic musculoskeletal injuries
- 592 Reported on the performance of alternative helmet fitting systems to prevent head injury, which will provide critical analysis to materiel developers in helmet fabrication.
- 1209 Verified that proposed animal models were strong predictors of human blunt trauma injury and will produce biomedically valid design criteria for body armor developers.
- 633 Evaluated five technologies for use in rapid water microbiological contamination test kits including competing efforts in genetic recognition and identification of microbes. The selected kit will provide for rapid analysis of environmental hazards to deploying soldiers.

Total 9072

FY 2001 Planned Program

- 1500 Characterize the effect of head and eye movement on heat dispersion through the retina to improve thermal retinal injury models and improve standards for protection.
- 1026 Determine risk of eye injury to Army aircrew in helicopters equipped with cockpit airbag systems which will lead to guidelines designed to maximize aviator safety during in-flight mishaps.
- 1106 Conduct field studies for repeated jolt during ground troop training exercises, which will be used to develop countermeasures to reduce injury rates of soldiers in tactical vehicles.
- 500 Research methods to reduce the effect of the overlapping of visual fields in binocular helmet mounted displays that could increase performance rates.
- 1850 Extend the combined gas injury incapacitation predictive models to include irritant gases, which will reduce the potential for toxic inhalation injury.
- 1801 Refine mass property guidelines of head-supported devices, which will be used to create strategies to reduce injury rates among aviators due to the aviator helmet design.
- 642 Determine the role of rotational head injury in helmet design to develop effective strategies to reduce injury rates.
- 1877 Validate predictive finite element models of blunt trauma, incorporating impact measurement, response model, and injury correlates to the develop criteria for assessing the impact of blunt trauma injury.
- 243 Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs.

Total 10545

FY 2002 Planned Program

- 1440 Identify, through micro-gene array techniques, promising candidate pharmaceuticals to arrest apototic mechanisms that destroy healthy photoreceptors near the primary retinal injury site to enhance protective strategies for soldiers.
- 1490 Establish and test standard methodologies for evaluating restraint technologies for tactical vehicles and aircraft.
- 1495 Establish visual performance criteria for the integration of flat panel displays into helmet mounted displays. The results of this research will be to develop enhanced imaging and display technologies to optimize soldier performance in degraded battlefield environments (e.g. fog, smoke etc).
- 1390 Extend the combined gas injury incapacitation predictive models to include particles in aerosols to develop protective measures in smoke filled buildings and in tactical vehicles penetrated by enemy rounds.
- 1290 Validate standards for head-supported mass for aviator injury risk. This research will enhance soldier performance while causing a reduction in acute and chronic injuries due to the increased equipment requirements placed on the warfighter.
- 1285 Propose new standards for minimum impact performance for ground/airborne troop helmets to minimize injury and stress during military operations. This research will develop advanced protective technologies for aircrew and airborne elements of the Objective Force.
- 1538 Develop bioreporters of reproductive effects using genomic and proteomic technologies with C. elegans, to provide faster and comprehensive toxicological hazards assessment.
- 1480 Field neurobehavioral toxicity assay in support of ongoing monitoring programs for water-borne contaminants.

Total 11408

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

June 2001

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
2 - APPLIED RESEARCH	**0602787A - Medical Technology**	**879**

COST (In Thousands)	FY 2000 Actual	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	Cost to Complete	Total Cost
879 MED FACT ENH SOLD EFF	7892	8361	8747	0	0	0	0	0	0	0

A. Mission Description and Budget Item Justification: This supports "Medical" and "Survivability" technology areas of the Objective 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 ("skin-in") 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. Research under this project is conducted at the Aeromedical Research Laboratory, the Research Institute of Environmental Medicine, and the Walter Reed Army Institute of Research and its overseas laboratories. Major contract is with JAYCOR. Additionally, numerous Cooperative Research and Development Agreements (CRDAs) are held with universities and independent laboratories. This program supports the Objective Force transition path of the Transformation Campaign Plan (TCP).

FY 2000 Accomplishments

- 1250 Determined that neither smoking nor high cholesterol altered thermoregulation during exercise in hot conditions. Intermittent exercise did not alter the ability of a soldier's body to tolerate heat under conditions where sweat cannot evaporate to cool the body (known as uncompensable heat, such as in protective overgarments). This effort will help lead to the development of guidelines to maintain performance under adverse environmental conditions.
- 1035 Improved hydration guidelines for prevention of heat stress. The improved guidelines include conditions for over hydration and for low serum sodium levels. These improved guidelines will reduce serious illness produced by over-hydration, without reducing protection against environmental injury.
- 1144 Modeled the effect of the delivery of caffeine to mitigate sleep inertia and optimize vigilance. This will lead to the development of pharmacological strategies to optimize aviator performance.
- 777 Determined the effects of modafinil on the performance of sleep-deprived aviators, including negative potential side effects such as nausea and vertigo. This has lead to the identification of adverse reactions to aviator performance caused by pharmacological interventions using this drug.

FY 2000 Accomplishments (Continued)

- 957 Completed the development of the Total Accident and Incident Health Objectives Database. This is an epidemiological tool to track health behaviors and fitness levels and their relation to illness and injuries resulting from training and deployment. This tool will lead to accurate prediction of soldier fitness and performance levels.
- 700 Conducted a study to assess the utility of the Army's body fat standards as an indicator of health risk for cardiovascular disease leading to the development of guidelines which will positively impact the health of all soldiers.
- 964 Described the workload of senior leaders using biostatus monitors. Peaks and depressions in activity and sleep over seven consecutive days were observed that indicated critical periods of optimum cognitive performance. This research provides preliminary evidence for effects of cumulative stress on senior leader performance.
- 1065 Pursued potentially sensitive and easily identifiable behavioral markers for predicting Acute Mountain Sickness leading to the development of effective countermeasures.

Total 7892

FY 2001 Planned Program

- 2525 Simulate cardiovascular parameters and body fluid shifts to better predict initial stages of heat injury and to model effects of dehydration, which will positively impact soldier readiness through early identification of heat stress injury.
- 1731 Explore the potential of low dose amphetamines to mitigate sleep inertia and optimize vigilance in aviators leading to the development of fatigue countermeasures for aviators during sustained operations.
- 1000 Create statistical techniques to pattern behavioral changes between soldiers, to predict stress responses in deployed soldiers and optimize soldier performance.
- 479 Demonstrate specific economic benefit to behavioral interventions to reduce unintended pregnancy and sexually transmitted diseases in new military accessions. This research will provide an analysis of a behavioral intervention program.
- 600 Determine effects of mediators of soft tissue inflammation on acute mountain sickness. This will allow the formulation of effective countermeasures.
- 725 Transition a Spatial Disorientation in-flight pilot demonstration into the Initial Entry Rotary Wing training program. This demonstration will provide pilots insight into the effects of in-flight disorientation and corrective measures for its prevention.
- 1150 Use biomechanical research techniques to establish medical criteria to optimize efficiency and ensure safety of new individual soldier equipment for use by equipment developers (WC).

FY 2001 Planned Program (Continued)

- 151 Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs.

Total 8361

FY 2002 Planned Program

- 1197 Identify possible genetic markers of heat injury susceptibility. The results of this research will optimize the ability of the Objective Force to operate in all environments.
- 1360 Test FDA approved drugs that induce sleep without suppressing slow-wave sleep. This research will develop medical countermeasures to sustain performance when the opportunity for adequate rest is impaired or impossible due to combat conditions.
- 1050 Determine the role of the sympathetic nervous system in altitude acclimatization to improve monitoring of interventions that may accelerate adaptation to altitude. This research will reduce injury due to deployment to high altitude environments.
- 1290 Begin longitudinal studies of deployment stress in Reserve and National Guard units deploying to engage in Security and Support Operations (SASO) efforts. This research will allow the soldier to more adequately address the stress of the increased number of deployments to support peacekeeping and humanitarian mission deployments.
- 1190 Determine the impact of deployment tempo on the health of the military family.
- 1280 Determine if current Acute Mountain Sickness medication, acetazolamide, has the detrimental effect of reducing physical exercise performance.
- 1380 Evaluate new, non-pharmacological methods to enhance alertness based on ambulatory monitoring technologies.

Total 8747

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

June 2001

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
2 - APPLIED RESEARCH	**0602787A - Medical Technology**	**977**

COST (In Thousands)		FY 2000 Actual	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	Cost to Complete	Total Cost
977	EMERGING INFECTIOUS DISEASES	0	6893	7000	0	0	0	0	0	0	0

A. Mission Description and Budget Item Justification: The scientific and technical objectives of this project is to focus on accelerating development of infectious disease threat countermeasures necessary to support operations in nonindustrialized countries and those in which infrastructure has been damaged or destroyed. It will also fund the necessary research to counter the military operational impact of emerging infectious diseases. This program supports the Objective Force transition path of the Transformation Campaign Plan (TCP).

FY 2000 Accomplishments

Project not funded in FY 2000.

FY 2001 Planned Program

- 6688 Evaluate modified virus as carrier vehicle for administration of candidate malaria vaccines to increase immune response. Perform molecular re-engineering to reduce toxicity of two antimalarial drug candidates.

  Seek proteins measurable in blood that may reflect immune responses to infection with diarrheal disease organisms, or dengue fever virus, for rapid testing of vaccine candidates.

  Perform gene sequencing of infectious organisms to assist in designing scrub typhus vaccine. Produce genetically engineered strains of meningitis in order to identify improved vaccine candidates.
- 205 Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs.

Total 6893

FY 2002 Planned Program

•	7000	Begin animal testing of viral-carrier malaria vaccine candidates. Further test efficacy of molecular-modified antimalarial drugs, including assessment of ease of manufacture. Refine methods for rapid isolation and quantitative assessment of circulating proteins indicative of malaria and dengue fever immunity. Develop scrub typhus vaccine candidates based on gene sequencing efforts. Begin testing of genetically engineered meningitis strains.
Total	7000	