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

February 2002

BUDGET ACTIVITY
2 - Applied Research

PE NUMBER AND TITLE
0602787A - MEDICAL TECHNOLOGY

	COST (In Thousands)	FY 2001 Actual	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate
	Total Program Element (PE) Cost	108400	128798	67476	71682	75359	76221	77722
841	COMPUTER-ASST MINIMALLY INVASIVE SURGERY	13460	11306	0	0	0	0	0
845	BONE DISEASE RESEARCH PROGRAM	5768	2778	0	0	0	0	0
863	BTLFLD SURGICAL REPLAC	0	4664	0	0	0	0	0
869	T-MED/ADVANCED TECHNOLOGY	4295	4460	3311	3496	3555	3597	3705
870	DOD MED DEF AG INF DIS	23630	25452	30568	32195	34109	34545	35379
873	HIV EXPLORATORY RSCH	11142	10969	0	0	0	0	0
874	CBT CASUALTY CARE TECH	10004	9004	11461	12252	12849	13161	13457
878	HLTH HAZ MIL MATERIEL	10302	11306	12302	12733	13271	13268	13461
879	MED FACT ENH SOLD EFF	8210	8668	9834	11006	11575	11650	11720
964	INFORMATICS-BASED MED. EMERG DECIS TOOLS (IMED)	5768	0	0	0	0	0	0
967	DYE TARGETED LASER FUSION	3845	3374	0	0	0	0	0
96A	EMERGENCY HYPOTHERMIA	2884	2580	0	0	0	0	0
96B	REAL TIME HEART RATE VARIABILITY TECHNOLOGY	2404	0	0	0	0	0	0
977	EMERGING INFECTIOUS DISEASES	6688	6937	0	0	0	0	0
MA1	ARTHROPOD-BORNE INFECTIOUS DISEASE CONTROL	0	2500	0	0	0	0	0
MA2	DIABETES PROJECT	0	5100	0	0	0	0	0
MA3	MEDICAL AREA NETWORK FOR VIRTUAL TECHNOLOGY	0	8000	0	0	0	0	0
MA4	SPEECH CAPABLE PERSONAL DIGITAL ASSISTANT	0	1000	0	0	0	0	0
MA5	CENTER FOR INTERNATIONAL REHABILITATION	0	1400	0	0	0	0	0
MA6	DERMAL PHASE METER	0	600	0	0	0	0	0

MA7	VCT LUNG SCAN	0	3200	0	0	0	0	0
MA8	MONOCLONAL ANTIBODY BASED TECHNOLOGY	0	3000	0	0	0	0	0
MA9	OPERATING ROOM OF THE FUTURE	0	2500	0	0	0	0	0

A. Mission Description and Budget Item Justification: 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 2001	FY 2002	FY 2003
Previous President's Budget (FY2002 PB)	111696	82494	74304
Appropriated Value	112729	129694	0
Adjustments to Appropriated Value	0	0	0
a. Congressional General Reductions	0	-896	0
b. SBIR / STTR	-2796	0	0
c. Omnibus or Other Above Threshold Reductions	0	0	0
d. Below Threshold Reprogramming	-500	0	0
e. Rescissions	-1033	0	0
Adjustments to Budget Years Since FY2002 PB	0	0	-6828
Current Budget Submit (FY 2003 PB)	108400	128798	67476

Program Change Summary Explanation:

Significant Changes: FY02 - Congressional Adds totalling $47200K (as noted below) added to this PE.

FY02 - Congressional adds were made for the Anthropod-borne Infectious Disease Control, Project MA1 ($2500); Diabetes Project (Pitt), Project MA2 ($5100); Emerging Hypothermia for Advanced Combat Casualty and Delayed Resuscitation, Project 96A ($2600); Medical Area Networks for Virtual Tech, Project MA3 ($8000); Osteoporosis Research, Project 845 ($2800); Speech Capable Personal Digital Assist, Project MA4 ($1000); Center for International Rehabilitation, Project MA5 ($1400); Dermal Phase Meter, Project MA6 ($600); Minimal Invasive Surgery Simulator, Project 841 ($1400); Minimally Invasive Therapy (CIMIT), Project 841 ($5000); VCT Lung Scan, Project MA7 ($3200); Tissue Engineering Research, Project 863 ($4700); Monoclonal Anti-body Based Tech (Heteropolymer System), Project MA8 ($3000); Dye Targeted Laser Fusion, Project 967 ($3400); and Operating Room of the Future, Project MA9 ($2500).

Projects with no R-2A not listed/defined due to space limitations.

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

February 2002

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

COST (In Thousands)	FY 2001 Actual	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate
869 T-MED/ADVANCED TECHNOLOGY	4295	4460	3311	3496	3555	3597	3705

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 U.S. Army Aeromedical Research Laboratory, the U.S. Army Research Institute of Environmental Medicine, the U.S. Army Institute of Surgical Research, and the Walter Reed Army Institute of Research. Additional contributors include Los Angeles County and the University of Southern California Medical Centers. This program supports the Objective Force transition path of the Transformation Campaign Plan (TCP).

FY 2001 Accomplishments:

- 1896 - Demonstrated physiological status monitoring to measure physiological strain and developed a government off the shelf time series database and data management capabilities to predict individual soldier status. Developed a passive acoustic method for detecting air in the chest.
- 2399 - Evaluated new methods for the diagnosis and treatment of severe blunt chest injury and hemorrhage. Diagnostic techniques included noninvasive detection of changes in autonomic function.

  - Conducted applied research to support the Warfighter Physiological Status Monitor (WPSM) for assessing and predicting individual warfighter status.

  - Established the sensitivity of telemetrically monitored physiological changes to differing workload levels under various levels of sleep deprivation. Field studies demonstrated that laboratory models accurately portray the tactical environment.

Total 4295

FY 2002 Planned Program

- 1938 - Conduct applied research to measure the physiologic state of soldiers by testing and refining a prototype microwave /acoustic device to detect pneumothorax, hemothorax, and subdural hematoma through clothing and mission-oriented protective posture (MOPP) gear. Construct a prototype device based on the principles of pulse plethysmography and pulse wave transmission for the measurement of blood pressures to facilitate automated triage and diagnosis.
- 2522 - Develop and test a prototype system to detect a wounding event using a projectile's acoustic signature.. Establish a database of human physiological responses collected immediately after severe trauma.

  - Conduct applied research to assess warfighter health status. Develop knowledge management system to reduce information from WPSM and predictive and health risk models. Determine level of predictability of physiological markers for performance decre ments or increments in the aviation environment.

  - Utilize physiological status monitoring data acquisition and management capabilities to predict performance and health risk essential to commanders. This effort will be applied to the "Future Warrior" technology area seeking to optimize utilization of the individual soldier.

Total 4460

FY 2003 Planned Program

- 1299 - Conduct applied research to integrate a device based on principles of pulse plethysmography and pulse wave transmission in a far-forward casualty care platform to measure the physiologic state of soldiers.

  - Continue the collection of human physiological responses immediately after severe trauma from multiple civilian urban trauma systems.

- 2012 - Conduct validation studies for concurrent collection of physiological data and performance data and evaluate emerging technology for physiological sensors and telemetry systems in the aviation environment.

  - Create reliable, automated bioelectronic, embedded toxic hazard and imminent physiological threat sensors via enabling technologies, directly supporting the Objective Force "Future Warrior" technology area, improving soldier protection.

Total 3311

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

February 2002

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

COST (In Thousands)		FY 2001 Actual	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate
870	DOD MED DEF AG INF DIS	23630	25452	30568	32195	34109	34545	35379

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 Kenya Medical Research Institute, Kenya; Peptide Therapeutics, Cambridge UK; Nanogen, San Diego CA; ACAMBIS, Inc., Cambridge MA; and University of Alabama, Birmingham AL. This program supports the Objective Force transition path of the Transformation Campaign Plan (TCP).

FY 2001 Accomplishments:

- 8533 -Evaluated modified virus as carrier vehicle for administration of candidate malaria vaccines, increasing immune protection.

  -Evaluated strategies to enhance ability of DNA vaccines for malaria to stimulate the immune system and protect vaccinees from disease.

  -Determined human immune response factors that protect against malaria for use in modifying candidate vaccines to enhance immune response.

  -Discovered through genetic manipulation the function of specific malaria proteins to identify the best drug targets. Determined the three-dimensional structure of vital malaria proteins to identify drugs that can disrupt their function.

  -Performed “molecular re-engineering” to reduce toxicity of two antimalarial drug candidates.

- 7321 -Studied epidemiology of Campylobacter diarrhea to determine the most prevalent strains to guide vaccine development. Conducted a 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.

  -Designed and tested in animal models vaccine candidates for diarrhea-causing Shigella and enterotoxigenic E. coli (ETEC), including a vaccine expressing proteins from both, and a Campylobacter vaccine given with and without an immune booster.

FY 2001 Accomplishments: (Continued)

- 2040 -Investigated malaria, diarrhea, Hantavirus and dengue diagnostic tests to be applied to a common diagnostic device for biological defense and infectious disease threats.

  -Characterized a genetically modified candidate Group B meningitis vaccine, verifying that it exhibits reduced toxicity and high immune response.

- 5736 -Investigated an improved DNA vaccine candidate to protect against dengue fever.

  -Evaluated the protective efficacy of an orally-administered DNA vaccine against dengue strain 2 in mice.

  -Produced a pilot lot of candidate DNA vaccine directed against hantaviruses that cause hemorrhagic fever with renal syndrome; and evaluated different vaccine delivery methods for the vaccine to determine which method was superior.

  -Investigated 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. Conducted field trials on a component of an insect vector control system that consists of a rapid test to identify dengue virus in mosquitoes.

Total 23630

FY 2002 Planned Program

- 9655 -Validate a human malaria sporozoite challenge model for evaluating vaccines against vivax malaria.

  -Further test efficacy of molecularly-modified antimalarial drugs, including assessment of ease of manufacture.

  -Evaluate a candidate malaria DNA vaccine containing 9 components representing multiple phases of the parasite's life cycle in humans; produce the 9 components for boosting the DNA vaccine and complete pre-clinical testing.

  -Produce a candidate protein vaccine against the liver stage of malaria and initiate pre-clinical testing in animals.

  -Cultivate multiple strains of malaria parasites in mosquitoes that can be used to challenge candidate vaccine recipients to determine if the vaccine is protective.

  -Evaluate a combination vaccination consisting of the protein RTS,S vaccine and a blood-stage malaria protein for safety and protection in monkeys.

  -Evaluate the effectiveness on a new immune booster delivered with the protein RTS,S malaria vaccine.

FY 2002 Planned Program (Continued)

- 6886 -Develop a single Shigella vaccine candidate that could protect against all three major types of Shigella (S. flexneri, sonnei and dysenteriae) and evaluate its ability to stimulate an immune response against these 3 organisms in an animal model. Modify the candidate Shigella flexneri vaccine in an attempt to reduce side effects and test safety in animal models. Construct a hybrid Shigella-ETEC vaccine and test for its ability to stimulate an immune response against both of these causes of diarrhea in an animal model.
- 3536 -Identify and characterize strains of Group B meningitis bacteria for a multi-component vaccine that could protect against many strains and genetically engineer two candidate Group B meningitis vaccine strains to reduce toxicity and optimize the ability to stimulate immunity.

  -Assess antibody-based tests for the identification of militarily important pathogens causing dengue fever and scrub typhus.

  -Design a rapid diagnostic test for scrub typhus to assist in evaluation of vaccine efficacy and develop DNA-based diagnostic tests to detect antibiotic resistance in intestinal bacteria, for use in epidemiological studies.

  -Modify scrub typhus vaccine candidates based on gene sequencing efforts to make it more broadly protective. Create a chigger-challenge model for the evaluation of candidate scrub typhus vaccines in mice.
- 5375 -Conduct pre-clinical evaluation of candidate insect repellent compounds to replace DEET.

  -Modify dengue candidate DNA vaccine to improve its immune response. Refine methods for rapid isolation and ability to measure levels of circulating proteins indicative of dengue fever immunity.

  -Develop a combined candidate vaccine to protect against Rift Valley fever and Crimean Congo hemorrhagic fever viruses and test in animals to demonstrate feasibility of multi-agent hemorrhagic fever DNA vaccines.

  -Determine the role of neutralizing antibodies stimulated by DNA vaccines in protecting against hemorrhagic fever with renal syndrome in order to assess the importance of antibodies in protection against this disease.

  -Complete preclinical testing of a candidate hantavirus DNA vaccine to protect against hemorrhagic fever with renal syndrome in compliance with FDA standards.

Total 25452

FY 2003 Planned Program

- 14125 -Conduct preclinical studies of new analogs of macrolide antibiotics and antifolate compounds as new malarial prevention drugs.

  -Develop new animal models that better predict human safety and efficacy of antimalarial drugs.

  -Evaluate a candidate malaria DNA vaccine with a virally-delivered booster, containing 9 components representing multiple phases of the parasite's life cycle in humans. Complete pre-clinical testing of a candidate protein vaccine against the liver stage of the malaria parasite.

  -Cultivate multiple strains of malaria parasites in mosquitoes that can be used to challenge candidate vaccine recipients to determine if the vaccine is protective.

- 8382 -Complete preclinical testing of a modified S. flexneri candidate vaccine that can protect while having fewer side effects than the current vaccine candidates. Conduct preclinical studies of oral and intranasal Campylobacter vaccines.

  -Complete the combined Shigella-enterotoxigenic E. coli vaccine preclinical animal studies and construct a Shigella-Campylobacter hybrid vaccine candidate to support development of a multiagent anti-diarrheal vaccine that can protect against multiple causes of diarrhea with a single vaccine.

  -Produce cGMP lots of vaccine candidates to protect warfighters against diarrhea caused by ETEC.

- 1834 -Complete the genetic engineering, characterization and evaluation of three Group B meningococcal vaccine strains for use in production of a broadly protective vaccine to protect against this cause of meningitis, an infectious, potentially fatal disease that can affect recruits in basic training camps.

- 6227 -Conduct pre-clinical evaluation of DNA vaccines to protect against all 4 serotypes of virus causing dengue fever including evaluation of safety and immune response in monkeys.

  -Develop an animal challenge model for testing scrub typhus vaccine. Perform safety testing of vaccine against scrub typhus, a vector borne disease found in several areas of potential military action.

  -Submit an investigational new drug application to the FDA for testing a DNA based Hanta virus vaccine, a virus that causes pulmonary and hemorrhagic disease.

  -Produce cGMP DNA dengue virus vaccine and prepare Investigational New Drug (IND) to submit to the FDA. Test novel approaches for delivering dengue DNA vaccines.

  -Synthesize and evaluate new insect repellent candidates to replace DEET, the current repellent used by the military.

Total 30568

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

February 2002

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

COST (In Thousands)	FY 2001 Actual	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate
873 HIV EXPLORATORY RSCH	11142	10969	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 and SRA Technologies, Falls Church VA. This program supports the Objective Force transition path of the Transformation Campaign Plan (TCP).

FY 2001 Accomplishments:

- 11142 - Researched manufacturing processes, produced pilot lots of vaccine, and conducted clinical sample processing and storage activities in support of vaccine testing and development.

  - Investigated 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 studies of HIV virus and immune system factors that are associated with immunity to assist with design and development of an effective vaccine.

  - Conducted studies of two candidate vaccines in animal models to determine safety and efficacy for producing an immune response, which are necessary before studies are begun in humans.

Total 11142

FY 2002 Planned Program

- 10969 - Define HIV virus and immune system factors associated with immunity that will aid in vaccine design.

  - Develop HIV diagnostic testing algorithms applicable to battlefields and civil/military emergencies so that newly developed tests will be used efficiently and effectively in protecting health care providers and emergency response teams.

  - Investigate manufacturing processes and produce pilot lots of 3 candidate HIV vaccines that are directed against 2 subtypes of virus found outside of the United States and test these vaccines in animals .

  - Conduct epidemiological studies and evaluate suitability of potential study sites for HIV vaccine testing in Cambodia, Uganda, Kenya, South America and Tanzania.

  - Conduct studies of HIV-infected DoD beneficiaries, to include collection of data on disease progression, drug resistance, and epidemiology to identify additional treatment and prevention strategies.

Total 10969

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

February 2002

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

COST (In Thousands)		FY 2001 Actual	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate
874	CBT CASUALTY CARE TECH	10004	9004	11461	12252	12849	13161	13457

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 U.S. Army Institute of Surgical Research, and the Walter Reed Army Institute of Research. Major contractors include the University of Washington, Seattle, Washington ; the State University of New York at Buffalo and Monterey Biomedical, Inc., Scotts Valley California. This program supports the Objective Force transition path of the Transformation Campaign Plan (TCP).

FY 2001 Accomplishments:

- 1202 - Conducted applied research on a freeze-drying process for plasma to reduce the logistical burden of blood products on the battlefield.
- 2311 - Conducted applied research on novel methods to stop bleeding and limit blood loss by continuing the assessment of Food and Drug Administration (FDA)-approved drugs to prevent battlefield hemorrhage-related deaths.

  -Performed studies of a drug; (recombinant clotting factor VIIa) that indicated its usefulness for controlling hemorrhage in casualties that become cold after wounding.

  - Continued construction of a prototype high frequency-focused ultrasound device to stop bleeding in organs.
- 2944 - Conducted applied research on new strategies of resuscitation that can improve survival after hemorrhage. Compared controlled versus uncontrolled hemorrhage to reduce late end-organ damage following resuscitation from hemorrhagic shock.

  - Advanced the design of a second-generation eye oximeter to measure if the brain is getting enough oxygen.

  - Demonstrated the use of a lower body negative pressure chamber to optimize monitoring and care of patients following trauma injury.
- 2105 - Conducted 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.

FY 2001 Accomplishments: (Continued)

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

• 1442 -Contract award pending for this 1-year congressional add that will conduct research in methods to purify blood products right on the battlefield. It will fund Emergency Blood Purification for Combat Casualty Care.

Total 10004

FY 2002 Planned Program

• 1020 - Conduct applied research to reduce the logistical burden of blood products on the battlefield by refining plasma's freeze-drying process 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.

• 2707 - Conduct applied research on novel methods to stop bleeding and limit blood loss by selecting the most effective FDA-approved drugs 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.

- Continue the evaluation of the lower body negative pressure as a surrogate model of hemorrhagic shock.

• 2601 - Conduct applied research on new methods of resuscitation of various resuscitation fluids and recommending the best commercial off-the-shelf 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.

- Test a device to measure absolute cerebrospinal fluid pressure after head trauma to reduce deaths due to increased cranial pressure.

- Conduct animal trials of a molecular biology-based method to mitigate the effects of smoke inhalation and thereby lower the death rate.

Total 9004

FY 2003 Planned Program

- 1544 - Conduct applied research to reduce the logistical burden of blood products on the battlefield by animal testing of dried plasma for field application. Further refine drying procedures for red blood cells to replace refrigerated red cells on the battlefield.
- 3298 - Conduct applied research on novel methods to stop bleeding and limit blood loss by selecting the most effective FDA-approved drugs/devices that can be introduced either through veins or by spraying into body cavities through wounds.

  - Conduct animal tests and continue refinement of a prototype high frequency-focused ultrasound device that will stop bleeding in organs.

  - Conduct studies on promising drugs to restore blood clotting when the patient is cold and thereby reduce blood loss.
- 3655 - Conduct applied research in new methods of resuscitation by studying ways to maximize the delay achievable with low volume resuscitation.

  - Make recommendations on new drugs and biologics with the intent of developing an improved resuscitation solution.
- 1630 - Conduct applied research on novel methods to minimize, repair, and prevent injuries to hard and soft tissues by exploring novel methods of treating the victims of land mines and flechette (shrapnel) weapons.
- 1334 - Conduct applied research on new stroke drugs to find a method of reducing the severe complications of head trauma.

Total 11461

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

February 2002

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

COST (In Thousands)		FY 2001 Actual	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate
878	HLTH HAZ MIL MATERIEL	10302	11306	12302	12733	13271	13268	13461

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, 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. Intramural research is conducted at the U.S. Army Aeromedical Research Laboratory, the U.S. Army 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 2001 Accomplishments:

- 1500 - Characterized the effect of head and eye movement on heat dispersion through the retina to improve thermal retinal injury models and improve standards for protection. Improved accessibility of the Laser Accident and Incident registry with a CD ROM version to assist in the awareness and assessment of laser eye injuries.
- 1666 - Determined risk of arm and eye injury to Army aircrew in helicopters equipped with cockpit airbag systems, which led to design modification guidelines to maximize aviator safety during mishaps.
- 1978 - Selected critical parameters for food and water contamination detection analysis from emerging technologies to enhance and facilitate assessment capabilities for deployed personnel.
- 1982 - Completed epidemiological studies of neck injury in operational aviation environments.
- 1299 - Determined the role of rotational head injury in helmet design to develop effective strategies to reduce injury rates. Determined the risk of injury to aviators from helmet-mounted displays worn during helicopter crashes and evaluated potential countermeasures.

FY 2001 Accomplishments: (Continued)

- 1877 - Validated predictive models of blunt trauma, incorporating impact measurement, response model, and injury correlates to develop and assess the predictors of blunt trauma injury.

Total 10302

FY 2002 Planned Program

- 1310 - Identify, through microgene array techniques, promising candidate pharmaceuticals to mitigate loss of healthy photoreceptors to enhance protective strategies for soldiers.
- 1428 - Establish and test standard methodologies for evaluating restraint technologies for tactical vehicles and aircraft. Deliver model of aircrew airbag interaction in rotary-wing crash environment.
- 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.
- 1490 - 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.
- 1290 - Propose standards for head-supported mass for injury risk. This research will enhance soldier performance while reducing acute and chronic injuries due to increased load-bearing requirements placed on the warfighter.
- 1285 - Analyze rotational head injury in helmet design findings to develop effective strategies to reduce injury rates. Propose and assess new impact protection concepts for airborne troop helmets.
- 1528 - Research indicators of reproductive effects using genomic and proteomic technologies with C. elegans, to provide faster and comprehensive toxicological hazards assessment.
- 1480 - Conduct field studies for repeated jolt during ground troop training exercises, which will validate proposed Health Hazard Assessment methods and the American National Standards Institute standards.

Total 11306

FY 2003 Planned Program

- 1771 - Evaluate and determine efficacy of neuroprotectants and/or steroid combinations targeted to minimize secondary neuronal injury from battlefield lasers and refine operational exposure limits to ensure the ocular health of deployed elements of the Objective Force.
- 1523 - Define injury thresholds for dynamic responses in restraint systems for Army ground and air vehicles. This research will provide enhanced protection while in tactical vehicles and aircraft for the elements of the Objective Force.
- 1686 - Extend the combined gas injury incapacitation models to include physical exertion. The results of this research will be to investigate protective measures for the warfighter against toxic substances potentially inhaled while in smoke-filled buildings and in tactical vehicles penetrated by enemy weapons.
- 1378 - Extend aviation head-supported mass standards to dismounted soldiers and validate head-supported mass neck injury thresholds and performance criteria. 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.
- 1334 - Determine new standards for minimum impact performance for Army aircrew/dismounted/airborne helmets. This research will support advanced protective technologies for aircrew and airborne elements of the Objective Force.
- 1367 - Mathematically model the effects of blunt trauma forces to soft tissue protected by body armor. The results of this study will be to increase survivability of the warfighter through body armor technology.
- 1497 - Provide validated repeated jolt guidelines and proposed standards for safe operations of tactical ground vehicles for use in the MANPRINT program.
- 1746 - Investigate a field deployable neurobehavioral toxicity assay in support of ongoing monitoring programs for water borne contaminants.

Total 12302

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

February 2002

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

COST (In Thousands)		FY 2001 Actual	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate
879	MED FACT ENH SOLD EFF	8210	8668	9834	11006	11575	11650	11720

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 U.S. Army Aeromedical Research Laboratory, the U.S. Army 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 2001 Accomplishments:

- 1955 - Simulated thermoregulatory and 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.
- 931 - Examined the potential of amphetamines to mitigate sleep inertia and optimize vigilance in aviators leading to the development of fatigue countermeasures for aviators during sustained operations. Determined the efficacy and impact on flight performance of temazepam for induction of sleep for resynchronization after shift change.
- 1479 - Created statistical techniques to pattern behavioral changes between soldiers, to predict stress responses in deployed soldiers and optimize soldier performance.
- 850 - Demonstrated that sea level ventilatory responses are not predictive of Acute Mountain Sickness (AMS) and determined the feasibility of ambulatory monitoring to manage AMS. This will enhance ability to manage forces at moderate and high altitude elevations.

FY 2001 Accomplishments: (Continued)

- 1104 - Demonstrated that body heat debt and not cutaneous heat flux provides the stimulus for human insulative cold acclimation, suggesting science-based approaches to better protect soldiers against cold, and field validated fluid replacement guidelines for hot weather training and evaluated the role of sodium loss and water over-consumption on the development of hyponatremia.
- 884 - Transitioned 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.
- 1007 - Used biomechanical research techniques to establish medical criteria to optimize efficiency and ensure safety of new individual soldier equipment for use by equipment developers.

Total 8210

FY 2002 Planned Program

- 1177 - Transition cold strain model to Java for compatibility with Army models. Study melatonin effects on cognitive ability, temperature regulation, and performance with integration into the SCENARIO model. Begin neural network model and sensitivity analysis of dehydration module and validate terrain coefficients in the model.
- 1301 - Test Food and Drug Administration (FDA) approved drugs that induce sleep without suppressing slow-wave sleep. Demonstrate efficacy of resynchronizing drugs for accelerating performance restoration following large eastward and westward deployments.
- 825 - Determine effectiveness of intermittent low barometric pressure, low oxygen exposures for inducing altitude acclimatization and demonstrate if moderate to high altitude residence ameliorates low blood oxygen levels and sustains cognitive performance without supplemental oxygen at between 3,000 and 4,300 meters.
- 1090 - 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 identify stressors associated with peacekeeping and humanitarian mission deployments.
- 1190 - Determine the impact of deployment operational tempo on the health of the military family.
- 1110 - Determine the effects of fatigue on susceptibility to in-flight disorientation, motion sickness, and high-level cognitive function in Army aviators.
- 980 - Delineate relationships between skin temperatures/wettedness, thermal discomfort, and cognitive performance.
- 498 - Develop methods for assessing effects on performance of gray level perception in head-mounted devices. Determine compatibility trade-offs of image intensification devices with color multifunction displays.

FY 2002 Planned Program (Continued)

- 497 - Evaluate sound localization by Army warfighters in realistic noise environments under hearing protection.

Total 8668

FY 2003 Planned Program

- 1070 - Model the effects of deployment stress on soldier and unit readiness. This research will identify stressors associated with peacekeeping and humanitarian mission deployments.
- 1230 - Determine if acetazolamide, the Acute Mountain Sickness (AMS) medication, has detrimental effects on physical exercise performance.
- 1130 - Define countermeasures for fatigue-induced increases in oculomotor and spatial orientation disturbances that will enhance warfighter performance capabilities.
- 1280 - Establish visual performance criteria for the integration of flat panel displays into helmet-mounted displays.
- 980 - Identify potential molecular markers of heat adaptation/maladaption. Determine the role of the central nervous system drive for dehydration-mediated reductions in exercise performance. Determine effectiveness of regional intermittent microclimate cooling.
- 1170 - Develop and complete testing of cold stress module and transition both the neural network and the high terrestrial coefficients into the model. Incorporate the biomedical model to optimize warfighter predictability.
- 1177 - Determine the effectiveness of modafinil for sustaining aviator performance in the in-flight environment using the UH-60 aircraft. Provide data on efficacy of modafinil compared to amphetamine and high dose caffeine. Provide comparative field evaluations of available countermeasures.
- 1240 - Develop animal hypothermia model that employs telemetry to monitor body temperature and cardiovascular responses.
- 557 - Characterize effects of hearing loss of free-field and virtual auditory localization. This research will help designers and leaders predict soldier performance.

Total 9834