

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

June 2001

BUDGET ACTIVITY
3 - ADV TECHNOLOGY DEV

PE NUMBER AND TITLE
0603002A - Medical Advanced 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	74381	221085	17541	0	0	0	0	0	0	0
800 TELEMEDICINE TESTBED	0	4315	1664	0	0	0	0	0	0	0
804 PROSTATE CANCER RSCH	2864	3963	0	0	0	0	0	0	0	0
810 IND BASE ID VACC&DRUG	7728	7995	8664	0	0	0	0	0	0	0
814 NEUROFIBROMATOSIS	0	16844	0	0	0	0	0	0	0	0
815 NATIONAL MEDICAL TESTBED	0	14862	0	0	0	0	0	0	0	0
818 ADVANCED CANCER DETECTION CTR	3341	3467	0	0	0	0	0	0	0	0
819 FLD MED PROT/HUM PERF	193	1676	556	0	0	0	0	0	0	0
840 COMBAT INJURY MGMT	5672	6362	2657	0	0	0	0	0	0	0
893 TISSUE REPLACEMENT	0	991	0	0	0	0	0	0	0	0
923 PROSTATE DIAGNOSTIC IMAGE	7160	0	0	0	0	0	0	0	0	0
929 ARTIFICIAL LUNG TECHNOLOGY	955	0	0	0	0	0	0	0	0	0
934 VOLUME ANGIOCAT	5729	5945	0	0	0	0	0	0	0	0
937 NERVOUS SYSTEMS STUDIES	0	5945	0	0	0	0	0	0	0	0
938 TISSUE ENGINEERING	0	2279	0	0	0	0	0	0	0	0
940 EPIDERMOLYSIS BULLOSA	955	2972	0	0	0	0	0	0	0	0
941 DIABETES RESEARCH	13365	13872	0	0	0	0	0	0	0	0
945 BREAST CANCER STAMP	1329	0	0	0	0	0	0	0	0	0
969 ALCOHOLISM RESEARCH	6684	8423	0	0	0	0	0	0	0	0
970 ENZYMATIC WOUND DISINFECTANT	1909	0	0	0	0	0	0	0	0	0
971 HIV RESEARCH	11247	9908	0	0	0	0	0	0	0	0
972 LASER VISION CORRECTION	1909	5449	0	0	0	0	0	0	0	0
973 RECOMBINANT VACCINE RESEARCH	1909	5945	0	0	0	0	0	0	0	0
974 SMART AORTIC RESEARCH	1432	0	0	0	0	0	0	0	0	0
975 PROTECTION AGAINST EMERGING INFECTIOUS DISEASES	0	3938	4000	0	0	0	0	0	0	0
97A BIOSENSOR RESEARCH	0	2478	0	0	0	0	0	0	0	0
97B BLOOD SAFETY	0	6936	0	0	0	0	0	0	0	0

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97C	CANCER CENTER OF EXCELLENCE	0	991	0	0	0	0	0	0	0	0
97D	CENTER FOR AGING EYE	0	1982	0	0	0	0	0	0	0	0
97E	CENTER FOR PROSTATE DISEASE RESEARCH	0	7431	0	0	0	0	0	0	0	0
97F	CHRONIC DISEASE MANAGEMENT	0	4459	0	0	0	0	0	0	0	0
97G	CHRONIC FATIGUE	0	1486	0	0	0	0	0	0	0	0
97H	CLINICAL ASSESSMENT RECORDING ENVIRONMENT	0	991	0	0	0	0	0	0	0	0
97I	DREAMS	0	9413	0	0	0	0	0	0	0	0
97J	ECHOCARDIOGRAM	0	1982	0	0	0	0	0	0	0	0
97K	FUNCTIONAL MAGNETIC RESONANCE IMAGING	0	495	0	0	0	0	0	0	0	0
97L	INTEGRATIVE MEDICINE DISTANCE LEARNING PROGRAM	0	793	0	0	0	0	0	0	0	0
97M	LIGAMENT HEALING	0	1486	0	0	0	0	0	0	0	0
97N	LUNG CANCER DETECTION	0	2972	0	0	0	0	0	0	0	0
97O	LUNG CANCER RESEARCH	0	4459	0	0	0	0	0	0	0	0
97P	REMOTE ACOUSTIC HEMOSTASSIS	0	3963	0	0	0	0	0	0	0	0
97Q	MICRO POSITRON EMISSION TOMOGRAPHY	0	991	0	0	0	0	0	0	0	0
97R	MOLECULAR AND CELLULAR BIOENGINEERING RESEARCH	0	595	0	0	0	0	0	0	0	0
97S	MOLECULAR GENETICS AND MUSCULOSKELETAL RESEARCH	0	7927	0	0	0	0	0	0	0	0
97T	NEUROTOXIN EXPOSURE TREATMENT	0	14862	0	0	0	0	0	0	0	0
97U	OCULAR FATIGUE MEASUREMENT	0	416	0	0	0	0	0	0	0	0
97V	POLYNITROXILATED HEMOGLOBIN	0	991	0	0	0	0	0	0	0	0
97W	SEATREAT CANCER TECHNOLOGY	0	1486	0	0	0	0	0	0	0	0
97X	SYNCHROTRON-BASED SCANNING RESEARCH	0	6936	0	0	0	0	0	0	0	0
97Y	VIRTUAL RETINAL DISPLAY TECHNOLOGY	0	3963	0	0	0	0	0	0	0	0

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97Z	TAFENOQUINE ANTIMALARIAL AGENT	0	1982	0	0	0	0	0	0	0	
98A	ARTIFICIAL HIP VOLUMETRICALLY CONTROLLED MFG	0	3468	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" and "Survivability" technology areas of the Objective Force. The primary goal of this program is to provide, with minimum adverse effects, maximum soldier survivability and sustainability on the integrated battlefield as well as in military operations other than war. This program element funds advanced technology development for the Department of Defense (DoD) core Vaccine and Drug Program, field medical protective devices, and combat injury management. The DoD core Vaccine and Drug Program provides, in accordance with Food and Drug Administration (FDA) regulations, drugs and vaccines for development that are effective protectants, treatments, and antidotes against military disease threats. Pilot and standard lots of candidate pharmaceutical-grade drugs, antidotes and vaccines are produced. 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 element 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).

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<u>B. Program Change Summary</u>	FY 2000	FY 2001	FY 2002	FY 2003
Previous President's Budget (FY2001 PB)	73252	16512	13491	0
Appropriated Value	74539	223132	0	
Adjustments to Appropriated Value	0	0	0	
a. Congressional General Reductions	0	0	0	
b. SBIR / STTR	-1910	0	0	
c. Omnibus or Other Above Threshold Adjustments	-295	0	0	
d. Below Threshold Reprogramming	3039	0	0	
e. Rescissions	-992	-2047	0	
Adjustments to Budget Years Since FY2001 PB	0	0	4050	
Current Budget Submit (FY 2002/2003 PB)	74381	221085	17541	0

Change Summary Explanation: Funding - FY 2002: Funding increased in support of Project 975- Protection Against Emerging Infectious Diseases (+4000)

One-year Congressional adds without R-2A Exhibits:

FY 2001

Project 804, Prostate Cancer Research (+4000)

Project 814, Neurofibromatosis Research (+17000)

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Project 815, National Medical Testbed (+15000)
Project 818, Advanced Cancer Detection (+3500)
Project 893, Wound Healing (+1000)
Project 934, Volume AngioCAT (+6000)
Project 937, Neuroscience Research (+6000)
Project 938, Tissue Repair (+2300)
Project 940, Epidermolysis Bullosa (+3000)
Project 941, Diabetes Projects (+14000)
Project 969, Alcoholism Research (+8500)
Project 971, HIV Research (+10000)
Project 972, Laser Vision Correction (+5500)
Project 973, Recombinant Vaccine Research (+6000)
Project 97A, Biosensor Research (+3500)
Project 97B, Blood Safety (+7000)
Project 97C, Cancer Center of Excellence (+1000)
Project 97D, Center for Aging Eye (+2000)
Project 97E, Center for Prostate Disease Research (+7500)
Project 97F, Chronic Disease Management (+4500)
Project 97G, Chronic Fatigue (+1500)
Project 97H, Clinical Assessment Recording Environment (CARE) (+1000)
Project 97I, Disaster Relief and Emergency Medical Service (DREAMS) (+9500)
Project 97J, Echocardiogram (Far Forward Echocardiogram Device) (+2000)
Project 97K, Functional Magnetic Resonance Imaging (+500)
Project 97L, Integrative Medicine Distance-learning Program (+800)
Project 97M, Ligament Healing (+1500)
Project 97N Lung Cancer Detection (CT) (+3000)
Project 97O, Lung Cancer Research (+4500)
Project 97P, Remote Acoustic Homostasis (+4000)
Project 97Q, Micro Positron Emission Tomography (+1000)
Project 97R, Molecular and Cellular Bioengineering Research (+600)
Project 97S, Molecular Genetics and Musculoskeletal Research Program (+8000)
Project 97T, Neurotoxin Exposure Treatment (+15000)
Project 97U, Ocular Fatigue Measurement (+420)
Project 97V, Polynitroxylated Hemoglobin (+1000)

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Project 97W, SEATreat Cancer Technology (1500)
Project 97X, Synchrotron-based Scanning Research (+7000)
Project 97Y, Virtual Retinal Display Technology (+4000)
Project 97Z, Tafenoquine Anti-malarial Agent (+2000)
Project 98A, Artificial Hip Volumetrically Controlled Manufacturing (+3500)

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BUDGET ACTIVITY 3 - ADV TECHNOLOGY DEV				PE NUMBER AND TITLE 0603002A - Medical Advanced Technology					PROJECT 800	
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
800 TELEMEDICINE TESTBED	0	4315	1664	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 developing and demonstrating future medical concepts of operations, operational architectures, and operational requirements to support forward echelon telemedicine presence, medical command and control, and collaborative planning tools for mission planning and rehearsal. It funds development, evaluation, and demonstration of prototype advanced technology concepts and materiel for provision of enhanced Force Health Protection. This program supports the Objective Force transition path of the Transformation Campaign Plan (TCP).

FY 2000 Accomplishments

Program not funded in FY 2000.

FY 2001 Planned Program

- 1696 This Project is a New Start previously funded by Program Elements/Projects: 00602787A/869 and 00602787A/874.
 - Evaluate modeling and simulation capabilities to provide commanders with capabilities to tailor deploying medical forces as part of Joint Medical Operations - Telemedicine Advanced Concept Technology Demonstration (ACTD).
 - Select the leave-behind capability package that will be evaluated by the U.S. Pacific Command during the transition phase of the ACTD and refine operational concepts.
 - 2491 A non-recurring Congressional add for secure telemedicine.
 - 128 Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs.
- Total 4315

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BUDGET ACTIVITY
3 - ADV TECHNOLOGY DEV

PE NUMBER AND TITLE
0603002A - Medical Advanced Technology

PROJECT
800

FY 2002 Planned Program

- 1664 Field a leave-behind capability and evaluate its robustness as a follow on of the Joint Medical Operations - Telemedicine ACTD. This will allow the users to further refine the operational and materiel concepts for employment of telemedicine in deployed military environments. Refine the logistical support concepts.

Total 1664

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BUDGET ACTIVITY
3 - ADV TECHNOLOGY DEV

PE NUMBER AND TITLE
0603002A - Medical Advanced Technology

PROJECT
810

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
810 IND BASE ID VACC&DRUG	7728	7995	8664	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 developing medical countermeasures for naturally occurring diseases that are militarily significant due to their potential impact on military operations. Medical countermeasures will protect the force from infection and sustain operations by preventing hospitalization 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 Israel Defense Force Medical Corps, Israel; Promed Trading, SA, Panama; the Armed Forces Research Institute of Medical Science, Bangkok, Thailand; 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

- 4080 Began FDA approved human clinical trials of new malaria vaccine candidates. Completed pre-clinical trials, in monkeys, of additional candidates and of alternate immunization schedules. Completed pre-clinical evaluation of candidate antimalarial drug extracted from artemisia plant.
- 1507 Initiated human clinical trials of candidate shigella dysentery vaccine. Continued preclinical and human clinical studies, of Enterotoxigenic Esherichia coli (ETEC) and Campylobactor candidate vaccines and infections.
- 1191 Began laboratory and field evaluations of potential new insect repellants; prepared two modified meningitis vaccines for preclinical and clinical evaluation.
- 950 Evaluated diagnostic tests for encephalitis and hemorrhagic fever infections.

Total 7728

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PROJECT
810

FY 2001 Planned Program

- 4832 Initiate human trials of a malaria DNA vaccine followed by a viral delivered malaria vaccine boost. Prepare sufficient blood stage and mosquito stage malaria vaccines for preclinical animal studies and human challenge trials. Complete preclinical efficacy, dosing, and toxicology evaluations as required by the FDA for artemisinic acid, the leading candidate drug to treat multi-drug resistant and severe and complicated malaria. Manufacture other antimalarial candidates for preclinical pharmacokinetic and toxicology studies.
- 2088 Conduct human trials of a Shigella flexneri live vaccine modified to reduce reactions in recipients, oral and transcutaneous vaccine candidates for ETEC and an oral vaccine candidate for Campylobacter.
- 903 Complete a safety and immunogenicity trial of candidate Group B meningitis vaccine to identify the best formulation. Conduct a clinical trial of Hepatitis E candidate vaccine to establish safety, immunogenicity, and dosing. Produce a single serotype dengue DNA vaccine and construct a virally delivered dengue vaccine candidate for safety testing in monkeys. Evaluate a Hantavirus DNA vaccine in monkeys. Validate a rapid antibody-based test for identifying Shigella in stool samples. Conduct concept exploration on insect vector control systems by conducting field trials to evaluate a rapid test to identify dengue virus in mosquitoes.
- 172 Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs.

Total 7995

FY 2002 Planned Program

- 5025 Begin clinical safety and immunogenicity studies of multivalent DNA and multivalent protein candidate vaccines for falciparum malaria. Start clinical safety and immunogenicity testing of candidate vaccines to protect against vivax malaria. Transition to advanced development an intravenous drug formulation for the treatment of severe and complicated malaria.
- 1164 Transition to development a Shigella dysenteriae vaccine to protect against this cause of debilitating diarrhea.
- 1661 Conduct a clinical trial of the leading candidate Group B meningitis vaccine. Conduct animal studies as required by the FDA to determine efficacy of a candidate plague vaccine that was developed for biological defense in preventing naturally acquired infection with the plague bacteria.
- 814 Conduct animal trials of a candidate dengue vaccine against all four dengue serotypes and complete a phase 1 human trial of a single serotype dengue candidate vaccine. Conduct animal studies to determine the efficacy of antibodies for the treatment and/or prophylaxis of hantavirus disease.

Total 8664

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PROJECT

810

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BUDGET ACTIVITY
3 - ADV TECHNOLOGY DEV

PE NUMBER AND TITLE
0603002A - Medical Advanced Technology

PROJECT
840

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
840 COMBAT INJURY MGMT	5672	6362	2657	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 as outlined in the Objective Force Medical Technology Area. The project funds prototypes of nonsystem-specific medical materiel items for far-forward medical management of shock and trauma and for casualty resuscitation including preclinical testing of candidate drug and biologic compounds and equipment to obtain data necessary for Food and Drug Administration (FDA) approval for human use. 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. The major contractor is Integrated Medical Systems, Signal Hill, CA. This program supports the Objective Force transition path of the Transformation Campaign Plan (TCP).

FY 2000 Accomplishments

- 1725 - Conducted advanced technology development of novel methods of stopping bleeding and enhancing the resuscitation capabilities for combat medics by testing a 10-week red blood cell storage solution to reduce the logistical burden on the battlefield, by testing fibrin foam formulations to control bleeding in animal models of hemorrhage, by starting clinical testing of a blood protein with anti-inflammatory properties that are protective after hemorrhage, and by continued testing of potential neuroprotective drugs in animal models to assess brain protection following trauma.

- 560 - Conducted advanced technology development on novel methods to minimize, repair, and prevent injuries to hard and soft tissues by evaluating modes of failure of bioabsorbable versus metallic soft tissue anchors in knee joints, investigating microencapsulated anti-inflammatory dental pulp-capping agents to enhance return to duty in far-forward locations, and beginning to test methods for the early diagnosis of low blood flow in limbs in patients with burns to the extremities.

- 3387 - Conducted advanced technology development of the Life Support for Trauma and Transport (LSTAT) platform to enhance patient care and transport far forward on the battlefield. This was a FY 2000 Congressional add.

Total 5672

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PROJECT

840

FY 2001 Planned Program

- 1215 - Conduct advanced technology development to evaluate novel drugs for reducing blood loss and enhancing hemostatic function in combatants wounded under severe cold conditions and test biologic agents to control massive internal bleeding. Examine methods to inactivate infectious agents in whole blood and red blood cells to enhance blood supply far forward.
- 645 - Conduct advanced technology development of devices to ease patient treatment on the battlefield. Complete the preclinical evaluation of an integrated anesthesia device to replace the outdated one currently in inventory. Perform field tests of a new, one-handed tourniquet.
- 328 - Conduct advanced technology development to establish a system for the collection of human trauma data at the locality of injury. Develop a lightweight, small device to sterilize dental instruments in the field environment to decrease logistical burden.
- 3986 - FY 2001 Congressional add to enhance and continue development of Life Support for Trauma and Transport (LSTAT).
- 188 - Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs.

Total 6362

FY 2002 Planned Program

- 1000 - Conduct advanced technology development to complete evaluation of drugs for reducing blood loss in cold casualties and complete study of methods for the delivery of biologic agents to control massive internal bleeding. Continue investigations to support the development of methods to inactivate infectious agents in whole blood to enhance blood supplies far forward.
- 1039 - Conduct advanced technology development of devices to ease patient treatment on the battlefield. Complete clinical trials of an integrated anesthesia device and the preclinical evaluation of a self-contained, 20-pound intensive care life support system. Complete technical testing of a personal oxygen generation system that will eliminate the need for oxygen cylinders on the battlefield.
- 618 - Conduct advanced technology development to collect human trauma data at the locality of injury. Enhance development of a lightweight, small device to sterilize dental instruments in the field environment.

Total 2657

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PROJECT
975

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
975 PROTECTION AGAINST EMERGING INFECTIOUS DISEASES	0	3938	4000	0	0	0	0	0	0	0

A. Mission Description and Budget Item Justification: The scientific and technical objectives for this project 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

- 3821 Conduct safety, immunogenicity, and first stage efficacy testing of three candidate malaria vaccines in Thailand.
Prepare FDA submissions for human testing of candidate vaccine against shigella, a major cause of diarrheal disease.
Conduct field evaluations of systems to kill dengue fever-transmitting mosquitoes, and to rapidly detect malaria-infected mosquitoes.
Further develop candidate DNA vaccine directed against hantavirus disease; explore delivery methods; produce pilot lot for initial human testing.
 - 117 Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs.
- Total 3938

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PROJECT
975

FY 2002 Planned Program

- 4000 Continue human testing of three candidate malaria vaccines in Thailand.
Initiate human volunteer trials of new shigella vaccine.
Expand scope of field trials of new mosquito-killing systems, and mosquito disease assay systems.
Initiate human safety and immunogenicity testing of DNA vaccine candidates for hantavirus infection.

Total 4000