

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R2 Exhibit)

February 2006

| BUDGET ACTIVITY 3 - Advanced technology development | | PE NUMBER AND TITLE 0603002A - MEDICAL ADVANCED TECHNOLOGY | | | | | |
|---|---------------------|--|---------------------|---------------------|---------------------|---------------------|---------------------|
| COST (In Thousands) | FY 2005 Estimate | FY 2006 Estimate | FY 2007 Estimate | FY 2008 Estimate | FY 2009 Estimate | FY 2010 Estimate | FY 2011 Estimate |
| Total Program Element (PE) Cost | 300328 | 300784 | 50757 | 58521 | 56804 | 53626 | 54117 |
| 800 TELEMEDICINE TESTBED | 1786 | 3296 | 3861 | 3967 | 4125 | 3994 | 4080 |
| 801 DEF WOMEN'S HEALTH RES | 0 | 1479 | 0 | 0 | 0 | 0 | 0 |
| 804 PROSTATE CANCER RSCH | 957 | 1971 | 0 | 0 | 0 | 0 | 0 |
| 810 IND BASE ID VACC&DRUG | 16618 | 18979 | 21237 | 21723 | 22442 | 21096 | 21242 |
| 814 NEUROFIBROMATOSIS | 23955 | 16758 | 0 | 0 | 0 | 0 | 0 |
| 819 FLD MED PROT/HUM PERF | 1323 | 1110 | 1172 | 1211 | 1267 | 1235 | 1267 |
| 840 COMBAT INJURY MGMT | 12356 | 19224 | 22507 | 29605 | 26882 | 25292 | 25478 |
| 893 TISSUE REPLACEMENT | 0 | 4534 | 0 | 0 | 0 | 0 | 0 |
| 923 PROSTATE DIAGNOSTIC IMAGE | 0 | 2760 | 0 | 0 | 0 | 0 | 0 |
| 929 ARTIFICIAL LUNG TECHNOLOGY | 0 | 1774 | 0 | 0 | 0 | 0 | 0 |
| 932 Minimally Invasive Surgery (CA) | 3449 | 1084 | 0 | 0 | 0 | 0 | 0 |
| 938 Tissue Engineering | 957 | 986 | 0 | 0 | 0 | 0 | 0 |
| 941 Diabetes Research | 4791 | 4238 | 0 | 0 | 0 | 0 | 0 |
| 945 BREAST CANCER STAMP PROCEEDS | 1874 | 0 | 0 | 0 | 0 | 0 | 0 |
| 954 DIGITAL X-RAY | 0 | 986 | 0 | 0 | 0 | 0 | 0 |
| 955 ASSISTIVE TECHNOLOGY | 0 | 2563 | 0 | 0 | 0 | 0 | 0 |
| 969 ALCOHOLISM RESEARCH | 3593 | 5520 | 0 | 0 | 0 | 0 | 0 |
| 97A BIOSENSOR RESEARCH | 2491 | 986 | 0 | 0 | 0 | 0 | 0 |
| 97B BLOOD SAFETY | 4600 | 3548 | 0 | 0 | 0 | 0 | 0 |
| 97D CENTER FOR AGING EYE | 1916 | 1971 | 0 | 0 | 0 | 0 | 0 |
| 97E CENTER FOR PROSTATE DISEASE RESEARCH AT WRAMC | 4120 | 0 | 0 | 0 | 0 | 0 | 0 |
| 97O LUNG CANCER RESEARCH | 9103 | 6604 | 0 | 0 | 0 | 0 | 0 |
| 97T NEUROTOXIN EXPOSURE TREATMENT | 24913 | 22672 | 0 | 0 | 0 | 0 | 0 |
| 97W SEATREAT CANCER TECHNOLOGY | 2875 | 0 | 0 | 0 | 0 | 0 | 0 |
| 97X SYNCHROTRON-BASED SCANNING RESEARCH | 9773 | 8379 | 0 | 0 | 0 | 0 | 0 |

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| BUDGET ACTIVITY | | PE NUMBER AND TITLE | | | | | | |
|--|--|---|-------|------|------|------|------|------|
| 3 - Advanced technology development | | 0603002A - MEDICAL ADVANCED TECHNOLOGY | | | | | | |
| 97Z | TAFENOQUINE ANTIMALARIAL AGENT | 7187 | 0 | 0 | 0 | 0 | 0 | 0 |
| FH4 | FORCE HEALTH PROTECTION - ADV TECH DEV | 0 | 1909 | 1980 | 2015 | 2088 | 2009 | 2050 |
| MB1 | ADV DIAGNOSTICS & THERAPEUTIC DIG TECH | 7187 | 986 | 0 | 0 | 0 | 0 | 0 |
| MB2 | BRAIN, BIOLOGY, AND MACHINE | 2875 | 1971 | 0 | 0 | 0 | 0 | 0 |
| MB3 | CENTER FOR INTEGRATION OF MEDICINE & INNOV TECH | 11500 | 10843 | 0 | 0 | 0 | 0 | 0 |
| MB4 | CENTER FOR UNTETHERED HEALTHCARE | 3833 | 986 | 0 | 0 | 0 | 0 | 0 |
| MB7 | HEMOGLOBIN BASED OXYGEN CARRIER | 1342 | 0 | 0 | 0 | 0 | 0 | 0 |
| MB9 | JOINT US NORWEGIAN TELEMEDICINE | 1727 | 986 | 0 | 0 | 0 | 0 | 0 |
| MC4 | SECURE TELEMEDICINE TECH PROGRAM | 957 | 1971 | 0 | 0 | 0 | 0 | 0 |
| MC7 | NATIONAL TISSUE ENGINEERING CENTER | 2396 | 1725 | 0 | 0 | 0 | 0 | 0 |
| MD1 | EMERGENCY TELEMED RESPONSE & ADV TECH | 1342 | 1971 | 0 | 0 | 0 | 0 | 0 |
| ME3 | INSTITUTE FOR RESEARCH AND EDUCATION | 3593 | 0 | 0 | 0 | 0 | 0 | 0 |
| ME4 | LASER FUSION ELASTIN | 4600 | 0 | 0 | 0 | 0 | 0 | 0 |
| ME9 | BEHAVIORAL/COMPARATIVE GENOMICS | 2491 | 986 | 0 | 0 | 0 | 0 | 0 |
| MF2 | ADVANCED PROTEOMICS (CA) | 1437 | 1479 | 0 | 0 | 0 | 0 | 0 |
| MF3 | BATTLEFIELD RESPIRATOR AND VENTILATOR (BRAV) (CA) | 1820 | 0 | 0 | 0 | 0 | 0 | 0 |
| MF9 | GENOMIC MEDICINE AND GENE THERAPY (CA) | 3257 | 2168 | 0 | 0 | 0 | 0 | 0 |
| MG1 | GYNECOLOGIC DISEASE PROGRAM (CA) | 4120 | 3351 | 0 | 0 | 0 | 0 | 0 |
| MG3 | MEDICAL TRAINING TECH ENHANCEMENT INITIATIVE (CA) | 957 | 1084 | 0 | 0 | 0 | 0 | 0 |
| MG5 | NATIONAL FUNCTIONAL GENOMICS CENTER (CA) | 8144 | 4928 | 0 | 0 | 0 | 0 | 0 |
| MG7 | ON-LINE MEDICAL TRAINING (CA) | 0 | 2070 | 0 | 0 | 0 | 0 | 0 |
| MG8 | OPERATING ROOM OF THE FUTURE (CA) | 3833 | 0 | 0 | 0 | 0 | 0 | 0 |

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| 3 - Advanced technology development | | 0603002A - MEDICAL ADVANCED TECHNOLOGY | | | | | | | |
| MG9 | PENNINGTON BIOMEDICAL CENTER (CA) | 2491 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| MH1 | PICTURE ARCHIVING AND COMMUNICATIONS SYSTEM (CA) | 1342 | 1676 | 0 | 0 | 0 | 0 | 0 | 0 |
| MH2 | PROJECT COLLABORATION MATERIAL (CA) | 957 | 986 | 0 | 0 | 0 | 0 | 0 | 0 |
| MH3 | PROTEOMICS CENTER (CA) | 4120 | 2563 | 0 | 0 | 0 | 0 | 0 | 0 |
| MH4 | RAPID BIO-PATHOGEN DETECTION TECHNOLOGY (CA) | 0 | 986 | 0 | 0 | 0 | 0 | 0 | 0 |
| MH5 | REGIONAL ANESTHESIA AND PAIN MGMT INITIATIVE (CA) | 5749 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| MH6 | RUGGED TEXTILE ELECTRONIC GARMENTS (CA) | 1437 | 1084 | 0 | 0 | 0 | 0 | 0 | 0 |
| MH7 | STUDY OF HUMAN OPERATOR PERFORMANCE (CA) | 2396 | 1479 | 0 | 0 | 0 | 0 | 0 | 0 |
| MH8 | ACCEL DIAGNOSIS-DIGITAL IMAGING PATTERN RECOG (CA) | 2684 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| MH9 | ADVANCE OF NON-INVASIVE GLUCOSE MONITORING (CA) | 957 | 1676 | 0 | 0 | 0 | 0 | 0 | 0 |
| MI1 | CLINICAL ED INSTITUTE/SURGERY INTERACTIVE SYS (CA) | 957 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| MI2 | AD IMAGE PROCESSING TECH FOR BIOMED INFORMATICS | 959 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| MI3 | ADVANCES IN BREAST CANCER CARE THERAPY (CA) | 1245 | 1676 | 0 | 0 | 0 | 0 | 0 | 0 |
| MI4 | ALLIANCE FOR NANOHEALTH (CA) | 2684 | 2070 | 0 | 0 | 0 | 0 | 0 | 0 |
| MI5 | BEHAVIORAL GENOMICS SLEEP APNEA RESEARCH (CA) | 957 | 986 | 0 | 0 | 0 | 0 | 0 | 0 |
| MI6 | CANCER VACCINE (CA) | 3257 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| MI7 | COLLABORATIVE IN ADVANCED EMR WITH THE ARMY GUARD | 2396 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| MI8 | FULL-FEATURED PATIENT MONITOR WITH DEFIBRILLATOR | 1437 | 986 | 0 | 0 | 0 | 0 | 0 | 0 |
| MI9 | EMERGENCY EYE CARE PROGRAM (CA) | 957 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| MJ1 | EXTRA CORPOREAL MEMBRANE | 5749 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

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| 3 - Advanced technology development | | 0603002A - MEDICAL ADVANCED TECHNOLOGY | | | | | | |
| | OXYGENATION AT TRIPLER | | | | | | | |
| MJ2 | FIBRINOGEN BANDAGES FOR BATTLEFIELD WOUNDS (CA) | 3354 | 2464 | 0 | 0 | 0 | 0 | |
| MJ3 | FORT DETRICK TECHNOLOGY TRANSFER INITIATIVE (CA) | 957 | 0 | 0 | 0 | 0 | 0 | |
| MJ4 | HANDS FREE ELECTRONIC HEALTH RECORD (CA) | 957 | 986 | 0 | 0 | 0 | 0 | |
| MJ5 | IMPROVED LUNG CANCER MGMT-ADV IMAGING TECH (CA) | 2012 | 0 | 0 | 0 | 0 | 0 | |
| MJ6 | LEISHMANIASIS PREVENTION TREATMENT & DIAGNOSIS | 7187 | 0 | 0 | 0 | 0 | 0 | |
| MJ7 | LIGHT-BASED SELF TREATMENT FOR PFB (CA) | 1437 | 986 | 0 | 0 | 0 | 0 | |
| MJ8 | WRAMC HUMAN BRAIN MAPPING FOR CMBT TRAUMA RSCH | 1727 | 0 | 0 | 0 | 0 | 0 | |
| MJ9 | MEDICAL ENTERPRISE MGMT FOR THE U.S. ARMY (CA) | 957 | 0 | 0 | 0 | 0 | 0 | |
| MK1 | MEDICAL M&S THROUGH SYNTHETIC DIGITAL GENES (CA) | 1437 | 986 | 0 | 0 | 0 | 0 | |
| MK2 | METROPLEX COMPREHENSIVE MEDICAL IMAGING RESEARCH | 6612 | 6900 | 0 | 0 | 0 | 0 | |
| MK5 | MOBILE I V SYSTEM (CA) | 2491 | 0 | 0 | 0 | 0 | 0 | |
| MK6 | ORPHAN DISEASE DRUG DISCOVERY PROGRAM (CA) | 1916 | 1676 | 0 | 0 | 0 | 0 | |
| MK7 | PEDIATRIC BRAIN TUMOR & NEUROLOGICAL DISEASE PRGM | 1437 | 1479 | 0 | 0 | 0 | 0 | |
| MK8 | PLASMA STERILIZER (CA) | 1342 | 1479 | 0 | 0 | 0 | 0 | |
| MK9 | PROPHET FOR COMBAT CASUALTY CARE (CA) | 480 | 0 | 0 | 0 | 0 | 0 | |
| ML1 | RARE BLOOD PROGRAM (CA) | 957 | 0 | 0 | 0 | 0 | 0 | |
| ML2 | SEAmEd ORAL HEALTH PROJECT (CA) | 1820 | 493 | 0 | 0 | 0 | 0 | |
| ML3 | SOLDIER-MOUNTED EYE-TRACKING & CONTROL SYSTEM (CA) | 1437 | 2464 | 0 | 0 | 0 | 0 | |
| ML4 | SuperQR Powder Development (CA) | 957 | 0 | 0 | 0 | 0 | 0 | |

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| 3 - Advanced technology development | | 0603002A - MEDICAL ADVANCED TECHNOLOGY | | | | | | | |
| ML5 | SURGICAL WOUND DISINFECTION & BIO AGENT DECON PROJ | 1342 | 1971 | 0 | 0 | 0 | 0 | 0 | 0 |
| ML6 | Tripler Army Medical Ctr eICU Remote Critical Care | 3833 | 986 | 0 | 0 | 0 | 0 | 0 | 0 |
| ML7 | UNIVERSAL MEDICAL AND SURGICAL PRODUCT CATALOG(CA) | 2396 | 2760 | 0 | 0 | 0 | 0 | 0 | 0 |
| ML8 | UNIVERSAL VACCINE DEVELOPMENT FOR BIOTERRORISM(CA) | 957 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ML9 | VASCULAR GRAFT RESEARCH FOR COMBAT SETTINGS (CA) | 1727 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| MM1 | WEIGHT MEASUREMENTS & STANDARDS FOR MIL PERSONNEL | 1820 | 1725 | 0 | 0 | 0 | 0 | 0 | 0 |
| MM2 | MEDICAL ADVANCE TECHNOLOGY INITIATIVES (CA) | 0 | 86425 | 0 | 0 | 0 | 0 | 0 | 0 |

A. Mission Description and Budget Item Justification: This program element (PE) funds advanced technology research for healthy, medically protected Soldiers, consistent with the Medical and Survivability technology areas of the Future Force. The primary goal of this program is to provide maximum Soldier survivability and sustainability on the battlefield as well as in military operations other than war. All medical research is conducted in compliance with U.S. Food and Drug Administration (FDA) regulations. The FDA requires thorough testing in animals (referred to as preclinical testing) to assure safety and efficacy prior to approving controlled clinical testing of experimental (previously unproven in humans) drugs, vaccines, and medical devices in humans. Normally clinical trials are conducted in three phases (Phase 1, 2 and 3) to prove safety and effectiveness of the drug/vaccine/device for the targeted disease/condition, including an increasing number of people in each subsequent phase. All test results are submitted to the FDA for evaluation to obtain approval for routine medical use. This PE funds maturation and demonstration of promising medical technologies identified during the applied research phase in the following areas: Militarily Relevant Infectious Diseases; Combat Casualty Care; and Military Operational Medicine. The Military Relevant Infectious Diseases effort focuses research on medical protection against naturally occurring diseases of military importance. Methods are identified and matured for prevention and treatment of infectious disease including conducting FDA-required preclinical and clinical safety and efficacy trials on candidate vaccines, prophylactic interventions, diagnostics, and therapeutic drugs. Methods for controlling disease-carrying insect vectors are refined and tested. The Combat Casualty Care effort matures and demonstrates methods for the care of trauma and burns associated with battlefield injuries. FDA preclinical and clinical safety and efficacy testing is included for candidate drugs, biologics, and diagnostics for resuscitation, treatment of injuries, and life support. Candidate medical devices and products for the warfighter include clotting drugs, freeze-dried plasma, neuroprotective drugs, handheld acoustic energy hemorrhage control devices, and an assisted automated critical care system. Candidate products for prevention of combat maxillofacial (face/neck) injuries and reduction of lost time due to dental disease are refined and demonstrated. The focus of the Military Operational Medicine (MOM) effort is on refining and demonstrating biomedical solutions that protect Soldiers and enhance their performance in the face of multiple stressors in operational and training environments. Products such as soft body armor and biomonitors are matured and demonstrated to determine their effectiveness in protecting Soldiers from injuries resulting from exposure to hazardous environments and materials. Prevention of health and performance degradation in military environments is another important objective of MOM research, which examines and refines selected physiological indicators and associated algorithms/sensors that may indicate performance degradation produced by operational stressors such as high altitude, extreme temperatures, hydration, fatigue, isolation, and sleep deprivation. Findings from research and treatment of Gulf War Illnesses are used to better understand military health issues to protect Service members against health threats in military deployments. The PE contains no duplication with any effort within the Military Departments and is related to, and

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0603002A - MEDICAL ADVANCED TECHNOLOGY

fully coordinated with, work funded in PE 0602787A. The cited work is consistent with Strategic Planning Guidance, the Army Science and Technology Master Plan (ASTMP), the Army Modernization Plan, and the Defense Technology Area Plan (DTAP). Work in this PE is performed by Walter Reed Army Institute of Research, Silver Spring, MD; U.S. Army Medical Institute of Chemical Defense, Aberdeen Proving Ground, MD; U.S. Army Medical Institute of Infectious Diseases, Fort Detrick, MD; U.S. Army Research Institute of Environmental Medicine, Natick, MA; U.S. Army Institute of Surgical Research, Fort Sam Houston, TX; U.S. Army Aeromedical Research Laboratory, Fort Rucker, AL; the Naval Medical Research Center, Silver Spring, MD and U.S. Army Medical Detachment Brooks, San Antonio, TX.

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PE NUMBER AND TITLE

3 - Advanced technology development

0603002A - MEDICAL ADVANCED TECHNOLOGY

| | FY 2005 | FY 2006 | FY 2007 |
|--|---------|---------|---------|
| <u>B. Program Change Summary</u> | | | |
| Previous President's Budget (FY 2006) | 299561 | 45160 | 50300 |
| Current BES/President's Budget (FY 2007) | 300328 | 300784 | 50757 |
| Total Adjustments | 767 | 255624 | 457 |
| Congressional Program Reductions | | -1314 | |
| Congressional Rescissions | | -3037 | |
| Congressional Increases | | 259975 | |
| Reprogrammings | 767 | | |
| SBIR/STTR Transfer | | | |
| Adjustments to Budget Years | | | 457 |

Software limitations preclude listing the One hundred fifteen FY06 Congressional adds totaling \$259975 that were added to this PE. To see the list of Congressional adds for this PE, please refer to the Conference Report on Defense Appropriations for Fiscal Year 2006, House Report 109-359, pages 356 to 358.

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|--|---|---------------------|---------------------|---------------------|---------------------|------------------------------|---------------------|
| BUDGET ACTIVITY 3 - Advanced technology development | PE NUMBER AND TITLE 0603002A - MEDICAL ADVANCED TECHNOLOGY | | | | | PROJECT 800 | |
| COST (In Thousands) | FY 2005 Estimate | FY 2006 Estimate | FY 2007 Estimate | FY 2008 Estimate | FY 2009 Estimate | FY 2010 Estimate | FY 2011 Estimate |
| 800 TELEMEDICINE TESTBED | 1786 | 3296 | 3861 | 3967 | 4125 | 3994 | 4080 |

A. Mission Description and Budget Item Justification: This project matures and demonstrates 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. The project funds development, evaluation, and demonstration of prototype advanced technology concepts and materiel pertaining to enhanced Force Health Protection. The major effort in this project is Sleep Research/Environmental Monitoring. Sleep Research evaluates the extent to which loss of sleep and fatigue can interfere with the Soldier's ability to perform missions and develop methods to mitigate these effects. Environmental Monitoring research matures and demonstrates an Environmental Sentinel Biomonitor, which can identify the presence of toxic industrial chemicals in water so that Soldiers may ascertain the potability of water. The cited work is consistent with Strategic Planning Guidance, the Army Science and Technology Master Plan (ASTMP), the Army Modernization Plan, and the Defense Technology Area Plan (DTAP). Work in this project is performed by U.S. Army Research Institute of Environmental Medicine (USARIEM), Natick, MA.

| <u>Accomplishments/Planned Program</u> | <u>FY 2005</u> | <u>FY 2006</u> | <u>FY 2007</u> |
|--|----------------|----------------|----------------|
| Sleep Research/Environmental Monitoring - In FY05, conducted comparative studies of higher order mental abilities that reflect militarily relevant capacities (judgment/decision-making, distinguishing friend from foe, course-of-action determination, and situational awareness) to determine which may be degraded by sleep loss; and determine whether any of the abilities can be restored through use of stimulants. In FY06, mature sensitive and repeatable measures to detect changes in higher order mental abilities with increasing levels of sleep deprivation and the effectiveness of a stimulant (caffeine) on restoration of these abilities. In FY07, will determine efficacy of caffeine in comparison to dextroamphetamine and modafinil (proprietary stimulants available by prescription only) for restoring operationally relevant high-order mental performance versus simple psychomotor performance; will integrate components into the Environmental Sentinel Biomonitor and conduct field test. | 1786 | 3296 | 3861 |
| Total | 1786 | 3296 | 3861 |

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February 2006

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|--|---|---------------------|---------------------|---------------------|---------------------|------------------------------|---------------------|
| BUDGET ACTIVITY 3 - Advanced technology development | PE NUMBER AND TITLE 0603002A - MEDICAL ADVANCED TECHNOLOGY | | | | | PROJECT 810 | |
| COST (In Thousands) | FY 2005 Estimate | FY 2006 Estimate | FY 2007 Estimate | FY 2008 Estimate | FY 2009 Estimate | FY 2010 Estimate | FY 2011 Estimate |
| 810 IND BASE ID VACC&DRUG | 16618 | 18979 | 21237 | 21723 | 22442 | 21096 | 21242 |

A. Mission Description and Budget Item Justification: This project matures and demonstrates medical countermeasures to naturally occurring infectious diseases that can adversely affect the Future Force. Infectious diseases pose a significant threat to operational effectiveness and forces deployed outside the United States. Countermeasures matured under this project will protect the force from infection during periods of sustained operations and prevent hospitalizations and evacuations from the theater of operations. Major efforts include development of vaccines against malaria, diarrhea, dengue, meningitis, and hemorrhagic fever; antimalarial drug candidate testing; and insect vector control and infectious disease diagnostic development. Of major importance to the military are the parasitic diseases malaria and leishmaniasis, the bacterial diseases responsible for diarrhea (caused by Shigella, enterotoxigenic Escherichia coli (ETEC), and Campylobacter), and viral diseases such as dengue fever. This project also matures improved materiel for control of insect/arthropod disease vectors and addresses a variety of infectious disease threats to deployed and mobilizing forces, including meningitis, viral encephalitis (inflammation of the brain), and viral hemorrhagic fevers (hemorrhagic fevers with renal syndrome (HFRS)). Improved diagnostic capabilities are also pursued that enable rapid battlefield identification and management of diseases and allow informed medical operational and tactical decisions. Program goals include preclinical and clinical testing of protein and DNA vaccines; testing new technologies to enhance effectiveness and duration of vaccines; compounding and testing multicomponent vaccines to provide protection against multiple disease strains; producing vaccines and antimalarial drugs under U.S. Food and Drug Administration (FDA)-regulated Good Manufacturing Practices (GMP) and demonstrating their safety and efficacy under FDA Investigational New Drug (IND) applications. Work is managed by the U.S. Army Medical Research and Materiel Command. The Army is lead service for infectious disease research within the DOD responsible for programming and funding all research on joint and Service-specific requirements, thereby precluding duplication of effort within the Military Departments. The cited work is consistent with Strategic Planning Guidance, the Army Science and Technology Master Plan (ASTMP), the Army Modernization Plan, and the Defense Technology Area Plan (DTAP). Work in this project is performed by the Walter Reed Army Institute of Research (WRAIR), Silver Spring, MD, and its overseas laboratories; U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), Fort Detrick, MD; and the Naval Medical Research Center (NMRC), Silver Spring, MD, and its overseas laboratories.

| Accomplishments/Planned Program | <u>FY 2005</u> | <u>FY 2006</u> | <u>FY 2007</u> |
|---|----------------|----------------|----------------|
| Malaria Vaccines - In FY05, performed preclinical testing of malaria liver stage vaccine components for integration into leading malaria vaccine candidate; and completed clinical safety testing of two promising malaria blood stage vaccine components. In FY06, continue clinical safety and efficacy testing of several promising malaria vaccine components to include testing of new adenovirus-based malaria vaccine before combining with the current RTS,S vaccine (hybrid protein fusing a malaria protein to the hepatitis B vaccine protein) which by itself does not provide strong protection against infection, in a prime boost strategy (i.e. prime humans with RTS,S, then administer a second immunization with the adenoviral vaccine, an approach thought to increase immune response of white blood cells in addition to producing antibody response); testing of a malaria blood stage cell surface protein vaccine in pediatric trial in Africa and safety and immunogenicity clinical trials of a second blood and liver stage protein vaccine in African adults. In FY07, will conduct additional clinical safety trial in adults or children as required/approved by the FDA to demonstrate safety and potential protection afforded by candidate multicomponent vaccines; will begin combined safety/immunogenicity clinical trial of multicomponent vaccines composed of combinations of RTS,S with additional blood and /or liver stage vaccine candidate and adenovirus vaccines once safety and efficacy has been demonstrated in clinical trials; and will establish partnership with industry for manufacturing of multicomponent vaccine for advanced clinical trial and future FDA licensing. The future objective is to downselect a multi-protein vaccine that will provide strong | 5077 | 5513 | 5906 |

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| BUDGET ACTIVITY | PE NUMBER AND TITLE | PROJECT | | |
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| 3 - Advanced technology development | 0603002A - MEDICAL ADVANCED TECHNOLOGY | 810 | | |
| protection from infection and, if infected, reduce severity and symptoms of disease. | | | | |
| Diarrheal Vaccines - In FY05, continued clinical testing of lead Campylobacter vaccine; and conducted clinical safety trials of one component of multiagent Shigella vaccine (vaccines which will prevent dysentery in US forces); produced a current GMP lot of diarrhea-causing enterotoxigenic Escherichia coli (ETEC) vaccine, along with protein encapsulated formulations which can be applied by intranasal spray. In FY06, complete a clinical efficacy trial with Campylobacter vaccine and continue clinical development of Shigella vaccines. In FY07, will conduct clinical efficacy trial in adult subjects to show induction of protective immune response by Shigella Invaplex intranasal vaccine (the most advanced vaccine candidate composed of bacterial surface material shed from the cells and to which most antibody binding would occur resulting in protection against Shigella dysentery); will prepare improved ETEC vaccine for clinical safety trial; and will continue clinical testing of other antidiarrheal vaccine candidates. | 3630 | 4357 | 5225 | |
| Dengue, Meningitis and Hemorrhagic Fever with Renal Syndrome (HFRS) Vaccines - In FY05, began preclinical testing of new modified dengue virus and DNA vaccine candidates; completed genetic modification of a third meningococcal strain vaccine component and prepared GMP lot of this vaccine component, and initiated preparation of the FDA required data package for a prototype meningitis vaccine to demonstrate proof of principle for this approach. In FY06, conduct additional clinical testing of best dengue vaccine candidates; conduct human clinical safety testing of vaccine and begin efficacy testing of a DNA-based Hemorrhagic Fever with Renal Syndrome (HFRS) vaccine; and begin clinical testing of additional component of the meningococcal vaccine. In FY07, will conduct clinical safety trial of a vaccine (active against several immunologically different subtypes of the meningococcal organisms); and will continue critical human efficacy testing of HFRS and dengue vaccines. | 4240 | 3599 | 4697 | |
| Antimalarial Drug Candidates - In FY05, completed fourth cohort of single dose safety study and initiated multi-dose clinical safety testing of intravenous Artesunate, a drug to treat severe malaria and to replace quinidine, the only FDA approved drug for severe malaria, a drug with known cardiotoxicity; continued to test/optimize new drugs against malaria for advancement to clinical testing. In FY06, complete safety trials and two clinical efficacy trials of Artesunate in Thailand and Kenya and select a second malaria prevention/prophylaxis candidate drug (based on evaluation of all candidates in development (see Project 870) for clinical testing. In FY07, will complete clinical testing of Artesunate and submit New Drug Application to FDA if the Agency accepts historical clinical data in place of performing expanded safety and efficacy testing; and will continue clinical testing of additional new prophylactic drugs to prevent malaria and a potential replacement for Larium. | 3056 | 3881 | 3310 | |
| Insect Vector Control and Infectious Disease Diagnostics - In FY05, continued dengue vector control system (DVCS) component product improvement; assessed potential point-of-care and hospital-based infectious disease diagnostic systems for effectiveness against leishmania and reickettsial. In FY06, transition the initial DVCS to preventive medical units; assess leishmania diagnostic systems in clinical testing, and mature approaches to supplement infectious disease diagnostics for use in common clinical laboratory diagnostic systems; continue sand fly vector control component testing and evaluation; evaluate a current FDA-approved drug for efficacy in treating cutaneous leishmania. In FY07, will conduct comprehensive field testing of sand fly control measures and transition to the Preventive Medicine Detachment tool kit; will continue to provide additional diagnostic sets for use in military clinical laboratories and point-of-care diagnostic sets for testing; and will transition leishmania diagnostic systems to advanced development or commercial partner. | 615 | 1629 | 2099 | |
| Total | 16618 | 18979 | 21237 | |
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|--|---|---------------------|---------------------|---------------------|---------------------|------------------------------|---------------------|
| BUDGET ACTIVITY 3 - Advanced technology development | PE NUMBER AND TITLE 0603002A - MEDICAL ADVANCED TECHNOLOGY | | | | | PROJECT 819 | |
| COST (In Thousands) | FY 2005 Estimate | FY 2006 Estimate | FY 2007 Estimate | FY 2008 Estimate | FY 2009 Estimate | FY 2010 Estimate | FY 2011 Estimate |
| 819 FLD MED PROT/HUM PERF | 1323 | 1110 | 1172 | 1211 | 1267 | 1235 | 1267 |

A. Mission Description and Budget Item Justification: This project supports the Medical and Survivability technology areas of the Future Force with laboratory validation studies and field demonstrations of biomedical products designed to protect, sustain, and enhance Soldier performance in the face of a myriad of environmental and physiological stressors and materiel hazards in training and operational environments. The major effort, Chemical and Bacterial Hazard Research, focuses on identifying stressors and methods of assessing risk. Research matures and demonstrates methodologies and tools associated with assessing weapon system user health risks, diagnostics as related to biomarker (indicator) identification of environmental health hazard exposures, predicting injury and assessing Soldier survivability, evaluating effectiveness of individual protective equipment, assessing drugs to sustain Soldier performance during continuous operations, and assessing health risks to Soldiers in operational environments. The cited work is consistent with Strategic Planning Guidance, the Army Science and Technology Master Plan (ASTMP), the Army Modernization Plan, and the Defense Technology Area Plan (DTAP). Work in this project is performed by Walter Reed Army Institute of Research (WRAIR), Silver Spring, MD, U.S. Army Center for Environmental Health Research (USACEHR), Fort Detrick, MD, and U.S. Army Medical Research Institute of Chemical Defense (USAMRICD), Aberdeen, MD.

| <u>Accomplishments/Planned Program</u> | <u>FY 2005</u> | <u>FY 2006</u> | <u>FY 2007</u> |
|--|----------------|----------------|----------------|
| Chemical & Bacterial Hazard Research - In FY05, developed methods using gene microarray technologies to identify biomarkers, which can be used in a health surveillance screening assay to determine if Soldiers have been exposed to toxic chemicals. In FY06, conduct tests using laboratory animals to determine and select animal biomarkers that indicate chemical exposure. In FY07, will identify and validate potential human biomarkers through extrapolation of animal data. | 1323 | 1110 | 1172 |
| Total | 1323 | 1110 | 1172 |

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R2a Exhibit)

February 2006

| | | | | | | | |
|--|---|---------------------|---------------------|---------------------|---------------------|------------------------------|---------------------|
| BUDGET ACTIVITY 3 - Advanced technology development | PE NUMBER AND TITLE 0603002A - MEDICAL ADVANCED TECHNOLOGY | | | | | PROJECT 840 | |
| COST (In Thousands) | FY 2005 Estimate | FY 2006 Estimate | FY 2007 Estimate | FY 2008 Estimate | FY 2009 Estimate | FY 2010 Estimate | FY 2011 Estimate |
| 840 COMBAT INJURY MGMT | 12356 | 19224 | 22507 | 29605 | 26882 | 25292 | 25478 |

A. Mission Description and Budget Item Justification: This project matures and demonstrates new medical technologies in support of the Future Force. Major efforts include hemorrhage control, blood and resuscitative fluids discovery and development, combat trauma therapies, far-forward medical systems development (including diagnostic and therapeutic medical devices), and combat casualty care bioinformatics and simulation development. Included are new candidate intravenous clotting drugs, advanced technologies for treating extremity injuries to bone and flesh, freeze-dried plasma to treat hemorrhage and further reduce the medical footprint, neuroprotective drugs to minimize consequences of head injury, preventive dental care technologies including peptides to fight dental disease, and remote triage technologies designed to maximize field medic resources. The "Warrior Medic," a promising Future Force medical technology capability, will enable the combat medic to rapidly assess casualty vital signs and link to other physiological monitors. Other key technologies funded include new and advanced resuscitation fluids and strategies for combat medic administration that improve survival of casualties with severe blood loss (shock) on the battlefield; an automated assisted critical care system for enhanced management, transport, and survival of stabilized casualties far-forward, within and outside of the battle area; and a handheld system employing acoustic energy to control internal hemorrhage for forward use at the battalion aid station. Selected technologies are integrated into Medical Mission Packages incrementally to provide comprehensive far-forward treatment for the Future Force. All research is conducted in compliance with U.S. Food and Drug Administration (FDA) requirements. The cited work is consistent with Strategic Planning Guidance, the Army Science and Technology Master Plan (ASTMP), the Army Modernization Plan, and the Defense Technology Area Plan (DTAP). Work in this project is performed by U.S. Army Institute of Surgical Research (USAISR), Fort Sam Houston, TX; U.S. Army Research Institute of Environmental Medicine (USARIEM), Natick, MA; and Walter Reed Army Institute of Research (WRAIR), Silver Spring, MD.

| Accomplishments/Planned Program | <u>FY 2005</u> | <u>FY 2006</u> | <u>FY 2007</u> |
|---|----------------|----------------|----------------|
| Hemorrhage Control, Blood and Resuscitative Fluids - including discovery and development of drugs, biologicals, and medical procedures to prevent or minimize secondary organ system injury and failure (including brain and spinal cord injury) after major trauma. In FY05, conducted studies in animals of a handheld device that stops bleeding with sound waves for use at the battalion aid station; studied in animals the effectiveness of candidate drugs and agents to enhance blood clotting and restore normal blood clotting; conducted clinical studies of freeze-dried plasma; finalized research for guidelines for the optimum resuscitation strategy; began studies of fluids that aid in oxygen transport and free radical scavenging; conducted investigations that indicate inhibiting complement activation (the body's natural reaction to trauma that can cause harmful inflammation and organ failure) reduces tissue damage associated with shock. In FY06, complete animal studies and sample analyses from coagulation studies; conclude comparative studies of resuscitation fluids; test FDA-approved complement inhibitors in additional animal models to confirm their safety. In FY07, will conduct multiple studies using blood components singly and in combination to match the effectiveness of whole blood in a combined injury/shock model; will conduct large scale testing of complement inhibitors in swine, prepare and analyze data for submission of Investigational New Drug application to the Food and Drug Administration and commence Phase 1 human safety trials upon approval; will finalize multiple studies in a collaborative effort across hemorrhage control, blood products, and resuscitation fluid programs; will complete data analysis and validate new regimens for treatment of shock in combat trauma. | 4303 | 9304 | 13220 |
| Combat Trauma Therapies - including discovery of drugs, biologicals, and medical procedures to minimize the immediate and long-term effects from battlefield injuries. In FY05, completed safety and efficacy studies of intranasal Ketamine in treatment of chronic malignant, | 2456 | 3966 | 3092 |

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R2a Exhibit)

February 2006

| BUDGET ACTIVITY | PE NUMBER AND TITLE | PROJECT | |
|---|---|--------------|--------------|
| 3 - Advanced technology development | 0603002A - MEDICAL ADVANCED TECHNOLOGY | 840 | |
| post-operative dental, and orthopedic injury pain with all data accepted by the Food and Drug Administration; conducted Phase 1 clinical tests of an improved tourniquet; matured and demonstrated wound-cleaning devices, antimicrobial bone graft substitutes, and lightweight materials for splints; and matured prototype of device to assess tissue viability. In FY06, complete testing of composite systems to validate cure time and rigidity to transition long bone splint to advanced development; and test combinations of growth factors that accelerate bone splint regeneration to select best bone substitute. In FY07, will begin human clinical trials of tissue viability assessment device; will transition best bone substitute material to advanced development; and will use the PHI model in further studies to evaluate the body's response mechanism to this type of injury. | | | |
| Far-Forward Medical Systems - including diagnostic and therapeutic medical devices and associated algorithms, software, and data processing systems for resuscitation, stabilization, life support, surgical support, and dental care. In FY05, conducted parallel studies of various antimicrobial compounds for safety and efficacy of preventing cavities; studied properties of application methodologies of an anticavity/antiplaque food additive to prevent dental disease; began to transition handheld Microimpulse radar (MIR) vital signs monitor to System Development and Demonstration; completed algorithms for detection of ballistic wounding, life signs, hydration, and sleep status in the prototype Future Force Warrior ensemble; and prepared to conduct human trials of a fieldable acoustic collapsed lung detector once human use approval is received; demonstrated proof of concept of closed-loop fluid infusion system; and started on oxygen and ventilation delivery system. In FY06, complete integration of the sensor suite, and generate algorithms with the Personal Area Network; complete integration of the initial capability with Future Force Warrior Advanced Technology Demonstration; evaluate relationships among variables that signal cardiovascular collapse and indicate the need to apply a Life Saving Intervention (LSI); demonstrate effectiveness of closed-loop oxygen and ventilation control and fluid resuscitation systems; and complete formulation of antimicrobial delivery vehicle for prevention of dental disease. In FY07, will complete analysis of data to develop and verify algorithms for prediction of cardiovascular collapse that indicate the need to apply a LSI; will complete clinical validation of closed-loop fluid infusion system; will evaluate neuroprotective drugs for reduction of morbidity following burn injury; and will establish antimicrobial activity profiles in animals for prevention. | 4325 | 4505 | 5495 |
| Combat Casualty Bioinformatics and Simulation - including a far-forward-compatible system for creation and management of patient records and theater regulation of patient flow and development of casualty simulations and durable, realistic simulators for initial and reinforcement training of care providers. In FY05, matured a prototype patient simulator with advances in materiel sciences, including realistic skin and physiologically accurate injuries, sensor technologies, miniaturization/packaging technology, and ad hoc wireless networking in collaboration with RDECOM. In FY06, complete testing of the RDECOM system to assess training effectiveness and interoperability. In FY07, will finalize prototype by incorporating user test results and transition to the Army Medical Department Center and School. | 1272 | 1449 | 700 |
| Total | 12356 | 19224 | 22507 |

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R2a Exhibit)

February 2006

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|--|---------------------|---|---------------------|---------------------|---------------------|---------------------|------------------------------|--|
| BUDGET ACTIVITY 3 - Advanced technology development | | PE NUMBER AND TITLE 0603002A - MEDICAL ADVANCED TECHNOLOGY | | | | | PROJECT FH4 | |
| COST (In Thousands) | FY 2005 Estimate | FY 2006 Estimate | FY 2007 Estimate | FY 2008 Estimate | FY 2009 Estimate | FY 2010 Estimate | FY 2011 Estimate | |
| FH4 FORCE HEALTH PROTECTION - ADV TECH DEV | 0 | 1909 | 1980 | 2015 | 2088 | 2009 | 2050 | |

A. Mission Description and Budget Item Justification: This project funds efforts that support Force Health Protection (FHP) with the goal of enhancing protection of Service members against health threats in military deployments both by increasing understanding of military health issues through advanced technology research and by applying findings from a decade of research on the etiology (cause and origin of disease) and treatment of Gulf War Illnesses (GWI). This project is conducted in close coordination with the Department of Veterans Affairs. The project is divided into five thrust areas: (1) global health monitoring, (2) health behavior interventions, (3) health risk communication, (4) health risk assessment methods, and (5) medical materiel safety. The goals of this project are to demonstrate the linkage between physical activity and a healthy lifestyle, and to determine the effectiveness of healthy lifestyle programs. Starting in FY06 this program transferred management from the Office of the Secretary of Defense to the U. S. Army. This project contains no duplication with any effort within the Military Departments. The cited work is consistent with Strategic Planning Guidance, the Army Science and Technology Master Plan (ASTMP), the Army Modernization Plan, and the Defense Technology Area Plan (DTAP). Work in this project is performed by the U.S. Army Research Institute of Environmental Medicine (USARIEM), Natick, MA; the Naval Health Research Center (NHRC), San Diego, CA; and the U.S. Army Center for Environmental Health Research (USACEHR), Fort Detrick, MD.

| <u>Accomplishments/Planned Program</u> | <u>FY 2005</u> | <u>FY 2006</u> | <u>FY 2007</u> |
|--|----------------|----------------|----------------|
| In FY06, demonstrate the cross-linkage between physical activity, weight management and healthy lifestyle to assess research findings and linkages to symptoms of the condition described as "chronic multi-symptom illness," which is a condition characterized by health problems that include a variety of chronic symptoms such as headache, fatigue, joint pain, rashes, respiratory problems, and neuropsychological difficulties. In FY07, will determine the effectiveness of current and state-of-the-art programs for healthy lifestyles (tobacco cessation and preventing alcohol abuse) in the military environment to assess research findings linking these approaches to mitigating the condition described as "chronic multi-symptom illness." | 0 | 1909 | 1980 |
| Total | 0 | 1909 | 1980 |