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ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2 Exhibit)									DATE February 1999	
BUDGET ACTIVITY 2 - Applied Research				PE NUMBER AND TITLE 0602787A Medical Technology						
COST (In Thousands)	FY1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY2004 Estimate	FY2005 Estimate	Cost to Complete	Total Cost
Total Program Element (PE) Cost	171362	138264	70136	68014	69125	69648	73135	76608	Continuing	Continuing
A825 Combat Maxillofacial Injury	1940	0	0	0	0	0	0	0	0	1940
A838 Neurotoxin Exposure Treatment	23420	19867	0	0	0	0	0	0	0	43287
A841 Computer Assisted Minimally Invasive Surgery	0	11425	0	0	0	0	0	0	0	11425
A843 Health Technology Roadmaps	0	1986	0	0	0	0	0	0	0	1986
A845 Bone Disease Research	0	2484	2500	0	0	0	0	0	0	4984
A869 Telemedicine/Advanced Technology	0	3341	5252	4495	4512	3332	3529	3599	Continuing	Continuing
A870 DoD Medical Defense Against Infectious Diseases	35486	23803	23794	24904	25725	26578	27965	29500	Continuing	Continuing
A872 Neurofibromatosis Research	9180	11425	0	0	0	0	0	0	0	20605
D873 HIV Exploratory Research	20414	14548	12634	11648	11095	10976	11473	11699	Continuing	Continuing
A874 Combat Casualty Care Technology	8364	10403	8580	8827	9102	9429	9896	10440	Continuing	Continuing
A878 Health Hazards of Military Materiel	7506	8671	9322	9684	9931	10240	10826	11395	Continuing	Continuing
A879 Medical Factors Enhancing Soldier Effectiveness	10530	7960	8054	8456	8760	9093	9446	9975	Continuing	Continuing
A919 Orthopedic Implant Research	2343	0	0	0	0	0	0	0	0	2343
A920 Prostate Cancer Research	37472	0	0	0	0	0	0	0	0	37472
A921 Ovarian Cancer Research	9369	0	0	0	0	0	0	0	0	9369
A927 Biocide Materials Research	5338	0	0	0	0	0	0	0	0	5338

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COST (<i>In Thousands</i>)	FY1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY2004 Estimate	FY2005 Estimate	Cost to Complete	Total Cost
A948 Portable Cardiopulmonary Bypass Pump and Oxygenator	0	1986	0	0	0	0	0	0	0	1986
A949 Advanced Cancer Detection	0	3478	0	0	0	0	0	0	0	3478
A950 Teleradiology	0	2980	0	0	0	0	0	0	0	2980
A951 Diagnostic and Surgical Breast Imaging	0	1987	0	0	0	0	0	0	0	1987
A952 Musculoskeletal Injuries	0	1987	0	0	0	0	0	0	0	1987
A953 Disaster Relief and Emergency Medical Services	0	9933	0	0	0	0	0	0	0	9933

A. Mission Description and Budget Item Justification: 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. 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 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 work in this PE is consistent with the Army Science and Technology Master Plan, Army force modernization plans, and Project Reliance. This program is managed primarily by the U.S. Army Medical Research and Materiel Command.

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B. Program Change Summary	<u>FY 1998</u>	<u>FY 1999</u>	<u>FY 2000</u>	<u>FY 2001</u>
Previous President's Budget (<u>FY 1999</u> PB)	160376	67255	66701	67834
Appropriated Value	165484	139255		
Adjustments to Appropriated Value				
a. Congressional General Reductions	-5108	-991		
b. SBIR / STTR	-3226			
c. Omnibus Adjustments	-1066			
d. Reprogramming from Navy	+7278			
e. Reprogramming from DHP	+8000			
Adjustments to Budget Years Since <u>FY 1999</u> PB			+3435	+180
Current Budget Submit (<u>FY 2000 / 2001</u> PB)	171362	138264	70136	68014

Change Summary Explanation: Funding: FY1998 – Congressional special interest funds appropriated in RDT&E, Navy (+7278) and DoD Defense Health Program (+8000)

realigned to this PE by DoD Internal Reprogrammings for proper program execution.

FY 1999 – Congressional special interest funds appropriated in RDTE (+70000) and additional funding for Combat Casualty Care Technology Project 874 (+2000).

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BUDGET ACTIVITY 2 - Applied Research	PE NUMBER AND TITLE 0602787A Medical Technology	PROJECT A825
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COST (In Thousands)	FY1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY2004 Estimate	FY2005 Estimate	Cost to Complete	Total Cost
A825 Combat Maxillofacial Injury	1940	0	0	0	0	0	0	0	0	1940

Mission Description and Justification: This project is a Congressional Special Interest Research add-on for support of military dental research efforts at Great Lakes Naval Station. This project has as its major applied research thrusts of new/improved methods and materiel for rapid simplified treatment of face and neck wounds and provision of field dental treatment.

- FY 1998 Accomplishments:**
- 845 Developed enhanced forward/deployable dental care through smaller, lighter, and efficient dental equipment, refined contaminant controls, improved field dental restorative materials, optimized bioactive implant materials and novel agents, vaccines, and materials for dental disease/maxillofacial trauma.
 - 791 Developed enhanced preventive and therapeutic dental initiatives such as novel antiplaque agents, dental sealants, and tobacco cessation programs.
 - 207 Developed intraoral sensors for monitoring physiological status of warfighters.
 - 97 Investigated the role of oral bacteria in neurological disease.
- Total 1940

FY 1999 Planned Program: Project not funded in FY 1999.

FY 2000 Planned Program: Project not funded in FY 2000.

FY 2001 Planned Program: Project not funded in FY 2001.

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BUDGET ACTIVITY 2 - Applied Research	PE NUMBER AND TITLE 0602787A Medical Technology	PROJECT A838
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COST (In Thousands)	FY1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY2004 Estimate	FY2005 Estimate	Cost to Complete	Total Cost
A838 Neurotoxin Exposure Treatment	23420	19867	0	0	0	0	0	0	0	43287

Mission Description and Justification: By Congressional direction, the purpose of this project is to conduct a research program on pathophysiology and treatment of neurodegenerative diseases, including Parkinson’s Disease, and including environmental and stress-exposure factors encountered in military operations that may be neurotoxic or lead to neurodegenerative diseases. An improved understanding of the pathophysiology of neurodegenerative diseases will form the basis of potential preventive measures against the effects of military threat agents and military operational hazards, and also lead to treatment interventions for Parkinson’s Disease.

FY 1998 Accomplishments:

- 23420 Funded a program of studies to meet these objectives by FY 2003:
 - Conduct a strong basic research program to understand the fundamental nature of neural cell death and dysfunction underlying neurodegenerative diseases.
 - Identify protective agents that may be useful in neural cell dysfunction.
 - Develop improved methods for early detection of neurodegenerative diseases.
 - Explore feasibility of new therapeutic strategies for neurodegenerative diseases involving transplantation and neuroprotection.
 - Explore feasibility of new therapeutic strategies for neurodegenerative diseases involving gene therapy and other novel treatments.
 - Investigate environmental factors that may be associated with neurodegenerative diseases.
 - Complete scientific peer review and programmatic selection of additional studies to round out the FY 1997 program portfolio.

Total 23420

FY 1999 Planned Program:

- 19341 Continue the program with awards to round out the existing portfolio.
- 526 Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs

Total 19867

FY 2000 Planned Program: Project not funded in FY 2000.

FY 2001 Planned Program: Project not funded in FY 2001.

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BUDGET ACTIVITY 2 - Applied Research	PE NUMBER AND TITLE 0602787A Medical Technology	PROJECT A841
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COST (In Thousands)	FY1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY2004 Estimate	FY2005 Estimate	Cost to Complete	Total Cost
A841 Computer Assisted Minimally Invasive Surgery	0	11425	0	0	0	0	0	0	0	11425

Mission Description and Justification: This project funds development of minimally invasive (surgery) technologies at the Center for Minimally Invasive Technology (CMIT) (at Massachusetts General Hospital).

FY 1998 Accomplishments: Project not funded in FY 1998.

FY 1999 Planned Program:

- 11123 Develop, at the Center for Minimally Invasive Technology (CMIT) at Massachusetts General Hospital, minimally invasive surgical technologies.
- 302 Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs

Total 11425

FY 2000 Planned Program: Project not funded in FY 2000.

FY 2001 Planned Program: Project not funded in FY 2001.

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BUDGET ACTIVITY 2 - Applied Research	PE NUMBER AND TITLE 0602787A Medical Technology	PROJECT A843
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COST (In Thousands)	FY1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY2004 Estimate	FY2005 Estimate	Cost to Complete	Total Cost
A843 Health Technology Roadmaps	0	1986	0	0	0	0	0	0	0	1986

Mission Description and Justification: By Congressional direction, this program funds the creation of technology roadmaps (e.g., plans for technologies and policies) that will facilitate efficient (advanced medical) technology development, transfer, and science-technology conversion.

FY 1998 Accomplishments: Project not funded in FY 1998.

FY 1999 Planned Program:

- 1933 Develop, at the Department of Energy Sandia National laboratories, plans for technologies and policies that maximize the value of various outputs of advanced technology R&D programs. Develop a methodology for determining medical applications for which technology can drive down DOD medical infrastructure costs. Demonstrate cost reduction potential and information security aspects of telemedicine applications and efforts by DOD.
 - 53 Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs
- Total 1986

FY 2000 Planned Program: Project not funded in FY 2000.

FY 2001 Planned Program: Project not funded in FY 2001.

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BUDGET ACTIVITY 2 - Applied Research	PE NUMBER AND TITLE 0602787A Medical Technology	PROJECT A845
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COST (In Thousands)	FY1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY2004 Estimate	FY2005 Estimate	Cost to Complete	Total Cost
A845 Bone Disease Research	0	2484	2500	0	0	0	0	0	0	4984

Mission Description and Justification: This program is intended to advance bone physiology research that may lead to strategies to improve bone health of young men and women, thereby enhancing military readiness by reducing the incidence of stress fracture during physically intensive training, and reducing the incidence of osteoporosis later in life. Individual health habits that can be encouraged in young recruits may have significant effects on achievement of peak bone mineral accretion and affect other aspects of short- and long-term bone health. Understanding bone remodeling processes triggered by physical training and the relationship to injury susceptibility will reveal appropriate training and other interventions that can reduce bone injuries in military personnel. Identification of predictors of stress fracture susceptibility, efficacious interventions, and treatment strategies for susceptible and injured service members can further reduce the impact of stress fractures on readiness. The ultimate benefits of this program include establishing optimal approaches to bone health of importance to all young Americans, reduction in lost duty time from skeletal injuries, and significant medical cost avoidance for DoD and the Department of Veterans Affairs. This program fills a specific and previously neglected niche in bone physiology research, supporting a wide range of basic science through applied clinical studies on biomechanical stress on the skeleton. This is also likely to leverage related areas of importance to the military such as muscle remodeling and it supports researchers who can address other questions fundamental to bone physiology and the understanding of bone diseases; research into the pathogenesis of bone diseases substantially supports understanding of normal processes.

FY 1998 Accomplishments: Project not funded in FY 1998.

FY 1999 Planned Program:

- 2418 Develop the program in these six thrust areas:
 - Conduct a strong basic research program to understand the fundamental nature of mechanical influences on bone cells.
 - Develop methodology to overcome technological barriers in imaging that will enable sequential studies of functional changes in bone.
 - Define the role of bone remodeling in stress fracture pathogenesis to determine if it would be beneficial or harmful to block remodeling in recruit training.
 - Investigate interventions (e.g., calcium-nutrient drinks, weak androgens, oral contraceptives) to improve bone health in men and/or women.
 - Describe changes in bone density and health in longitudinal studies of young men and women engaged in demanding training program.
 - Investigate treatments that increase rates of healing after stress fracture.
 - 66 Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs
- Total 2484

FY 2000 Planned Program:

- 2500 Expand and continue the program in these six thrust areas:

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BUDGET ACTIVITY 2 - Applied Research	PE NUMBER AND TITLE 0602787A Medical Technology	February 1999
- Conduct a strong basic research program to understand the fundamental nature of mechanical influences on bone cells.		
FY 2000 Planned Program: (continued)		
- Develop methodology to overcome technological barriers in imaging that will enable sequential studies of functional changes in bone.		
- Define the role of bone remodeling in stress fracture pathogenesis to determine if it would be beneficial or harmful to block remodeling in recruit training.		
- Investigate interventions (e.g., calcium-nutrient drinks, weak androgens, oral contraceptives) to improve bone health in men and/or women.		
- Describe changes in bone density and health in longitudinal studies of young men and women engaged in demanding training program.		
- Investigate treatments that increase rates of healing after stress fracture.		
Total	2500	
FY 2001 Planned Program: Project not funded in FY 2001.		
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BUDGET ACTIVITY 2 - Applied Research	PE NUMBER AND TITLE 0602787A Medical Technology	PROJECT A869
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COST (<i>In Thousands</i>)	FY1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY2004 Estimate	FY2005 Estimate	Cost to Complete	Total Cost
A869 Telemedicine/Advanced Technology	0	3341	5252	4495	4512	3332	3529	3599	Continuing	Continuing

Mission Description and Justification: Applied research 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). Research will focus on developing a wearable, integrated system to determine soldier physiological status. This will include developing the ability to quickly and accurately determine when a soldier is minimally impaired but still capable of functioning. By extension, work will also focus on identification and initial development of parallel and supporting technologies and systems, including telecommunications networks, teleconsultation technologies, and telerobotics.

FY 1998 Accomplishments: Project not funded in FY 1998.

FY 1999 Planned Program:

- 863 Modify the Land Warrior System to allow wound detection and remote triage communication between individual soldiers and the medic.
 - 600 Begin to develop a prototype wearable Warfighter Physiological Status Monitoring (WPSM) system for use at the Dismounted Battlespace Battle Lab (DBBL) that has a wireless "plug and play" sensor network (activity, pulse, core and skin temperature, geolocation, metabolic cost of marching) that collects and stores information in an open, standardized format.
 - 490 Continue development of an eye oximeter to assess cerebral blood oxygen content for measures of brain perfusion.
 - 450 Do concept experimentation program tests at the DBBL.
 - 200 Develop a portable teleradiology system to enhance diagnostic capability far forward.
 - 500 Support for Joint Medical Operations-Telemedicine Advanced Concept Technology Demonstration.
 - 150 Continue development of a Micro Impulse Radar which is used to assess cardiovascular function.
 - 88 Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs
- Total 3341

FY 2000 Planned Program:

- 244 Investigate accuracy and efficacy of first-generation physiological sensors to be used for far-forward diagnosis on the Land Warrior System.
- 1428 Support for Joint Medical Operations-Telemedicine Advanced Concept Technology Demonstration.
- 575 Develop intelligent instructional systems to facilitate adaptive learning of first responder diagnosis and treatment skills.
- 500 Develop first generation WPSM electronics for physiological monitoring of soldier status.
- 569 Interface WPSM system with Land Warrior Dead Reckoning Module to collect mission-specific physiological data from soldiers during field training exercises.

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BUDGET ACTIVITY 2 - Applied Research	PE NUMBER AND TITLE 0602787A Medical Technology	PROJECT A869												
<p>FY 2000 Planned Program: (continued)</p> <table border="0"> <tr> <td style="padding-left: 20px;">784</td> <td>Start artificial intelligence/sensor fusion protocols for WPSM to enhance diagnostic and treatment capabilities far forward.</td> </tr> <tr> <td style="padding-left: 20px;">500</td> <td>Develop first generation Warrior Medic electronics as elements for non-invasive monitoring of patient status.</td> </tr> <tr> <td style="padding-left: 20px;">250</td> <td>Demonstrate Warrior Medic medical decision assist algorithm for far-forward diagnosis and triage.</td> </tr> <tr> <td style="padding-left: 20px;">402</td> <td>Continue development of non-invasive sensors for Warrior Medic.</td> </tr> <tr> <td>Total</td> <td>5252</td> </tr> </table> <p>FY 2001 Planned Program:</p> <ul style="list-style-type: none"> • 644 Continue development of non-invasive sensors for Warrior Medic. • 780 Continue development of intelligent instructional systems to facilitate adaptive learning. • 612 Continued development of Warrior Medic and WPSM electronics. • 889 Utilize WPSM database, and data acquisition and management capability, to support the development and testing of modeling strategies to predict individual warfighter status. • 770 Explore and develop a variety of medical technology overlays to tactical computing/communicating capability in order to assess performance without injury and to compare data post-injury to pre-injury. • 800 Test artificial intelligence/sensor fusion protocols for WPSM. <table border="0"> <tr> <td>Total</td> <td>4495</td> </tr> </table>			784	Start artificial intelligence/sensor fusion protocols for WPSM to enhance diagnostic and treatment capabilities far forward.	500	Develop first generation Warrior Medic electronics as elements for non-invasive monitoring of patient status.	250	Demonstrate Warrior Medic medical decision assist algorithm for far-forward diagnosis and triage.	402	Continue development of non-invasive sensors for Warrior Medic.	Total	5252	Total	4495
784	Start artificial intelligence/sensor fusion protocols for WPSM to enhance diagnostic and treatment capabilities far forward.													
500	Develop first generation Warrior Medic electronics as elements for non-invasive monitoring of patient status.													
250	Demonstrate Warrior Medic medical decision assist algorithm for far-forward diagnosis and triage.													
402	Continue development of non-invasive sensors for Warrior Medic.													
Total	5252													
Total	4495													
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BUDGET ACTIVITY 2 - Applied Research	PE NUMBER AND TITLE 0602787A Medical Technology	PROJECT A870
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COST (In Thousands)	FY1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY2004 Estimate	FY2005 Estimate	Cost to Complete	Total Cost
A870 DoD Medical Defense Against Infectious Diseases	35486	23803	23794	24904	25725	26578	27965	29500	Continuing	Continuing

Mission Description and Justification: This project supports development of medical countermeasures to naturally occurring infectious diseases, a significant threat to forces deployed outside the United States. These countermeasures will protect the force from infection and sustain operations by preventing hospitalizations and evacuations from the theater of operations.

FY 1998 Accomplishments:

- 3000
 Identified a merozoite surface protein (MSP1[42]) as a candidate vaccine against the bloodstream phase of the malaria parasite, necessary for complete immune protection from malaria. Devised new *E. coli* plasmid expression systems for production of large quantities of *P. falciparum* antigens, necessary to produce reagents for evaluation of vaccine immune responses in clinical trials. Conducted study of sequestrin as a malaria immunogen in rhesus monkeys, necessary to discover additional candidate immunogens for clinical application. Collected 34 clinical isolates of *P. falciparum* as part of a library of isoates, necessary for studying genetic diversity as part of vaccine development. Implemented study of EBA-175 in 34 *Aotus* monkeys, a candidate vaccine for protection from blood-stage malaria. Began field-site development for clinical vaccine studies in Peru and Ghana. Confirmed high degree of sequence homology among malaria parasites from Indonesia compared to synthetic peptides representing potential vaccine immunogens; supports use of such peptides as vaccine immunogens. Studied several methods to augment immunogenicity of malaria DNA vaccines. Evaluated immunogenicity of “minigene vaccines” in mice as a means to induce a broad range of humoral and cellular protective responses; demonstrated protection from challenge in up to 50% of mice. Tested eight DNA vaccine candidates against *P. vivax* in *Aotus* monkeys; demonstrated immunogenicity but no protection.
- 3006
 Established a repository of culture-adapted, folate-resistant *P. falciparum* field isolates as a source of material for studying the molecular basis of drug resistance and for use as test isolates in assessing efficacy of candidate antifolate drugs. Completed full-length sequencing of cytochrome b in over 30 field isolates of *P. falciparum* and discovered no naturally occurring resistance to atovoquone, a candidate drug being developed by the DoD for treatment and prevention of malaria that will soon be approved for use, important for continuing malaria risk assessment and antimalarial drug development. Conducted in vitro drug susceptibility testing on over 3,000 candidate drug compounds, necessary for ongoing drug discovery. Discovered at least seven new classes of antimalarial drugs for further study and potential development. Demonstrated insignificant cross-resistance between mefloquine and artemisinin, a new candidate antimalarial under development by the DoD, important for ongoing development of this new drug and definition of expected efficacy. Demonstrated a high-level correlation between mefloquine and desbutylhalofantrine, another candidate antimalarial, suggesting a very limited effective geographic range for desbutylhalofantrine, given the widely distributed occurrence of resistance to

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<p>mefloquine. Using quantum chemical computational methods, identified electronic properties necessary for antimalarial activity of two classes of antimalarial compounds; this contributes to discovery of new antimalarial drugs for treatment and prevention. Discovered no resistance to artemisinin among field isolates of <i>P. falciparum</i> in Thailand in ongoing surveillance for emergence of artemisinin drug resistance, necessary for further drug</p> <p>FY 1998 Accomplishments: (continued)</p> <p>development activities related to this class of drugs. Using polymerase chain reaction (PCR) finger printing, confirmed high rates of chloroquine resistance among clinical isolates of <i>P. vivax</i> in Indonesia; this effort is necessary for ongoing disease risk assessment. Established a clinical field site for future antimalarial drug studies in Indonesia.</p> <ul style="list-style-type: none"> • 700 Developed an enzyme-linked immunosorbent assay (ELISA) for monitoring the immune response to candidate Shigella vaccines, necessary for understanding vaccine immunity or lack thereof in clinical testing. Conducted epidemiological and natural history studies of Shigella infection among children in Egypt. Documented overall annual incidence rates of one episode for every five people per year in this population. These studies were necessary for field-site preparation for future vaccine field studies. • 515 Demonstrated a wide range of phenotypic diversity among enterotoxigenic <i>Escherichia coli</i> (ETEC) isolates collected from Egyptian children, suggesting significant limits to the efficacy of the current candidate whole-cell ETEC vaccine, necessary for planning and designing efficacy trials of the ETEC vaccine. Demonstrated the presence, in breast milk of mothers living in ETEC-endemic areas of Egypt, of antibodies to specific virulence factors of ETEC, a prelude to studying the incidence and severity of homologous ETEC infection among breast-feeding infants. This contributed to defining and understanding correlates of immune protection from ETEC. • 810 Based on surveillance of <i>C. jejuni</i> infection among Army and Marine personnel deployed to Thailand during training and based on virulence studies in ferrets, selected additional strains of <i>C. jejuni</i> for potential inclusion in a second-generation, pentavalent, inactivated whole-cell vaccine for prevention of <i>C. jejuni</i> infection. Began development of an ELISA for quantification and standardization of key antigen content in vaccine candidates, necessary for eventual licensure of a successful vaccine. Conducted surveillance of Campylobacter infection among children in Egypt to characterize strains of Campylobacter among clinical isolates, necessary for future field efficacy trials of candidate vaccines for prevention of <i>C. jejuni</i> infection. • 350 Produced native and recombinant dengue antigens and attached them to platforms capable of supporting field diagnostic assay requirements. Identified field sites in Peru capable of supporting analysis of malaria diagnostic tests. Increased temperature stability of viral diagnostic reagents by lyophilizing them, demonstrating a technology that will be required in order to meet milestone exit criteria for all diagnostic devices. 		
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<ul style="list-style-type: none"> 1625 Using a candidate dengue type 2 nucleic acid vaccine in nonhuman primates, demonstrated nearly complete protection from challenge after four doses of vaccine, an important step for selection of vaccine candidate. Began development of two assays (plaque reduction neutralization assay and reverse transcriptase-PCR for detection of viremia) for assessment of immune response and protection in vaccinees, necessary for future efficacy testing of candidate vaccines. Began comparative evaluation of two candidate dengue vaccines (purified, inactivated vaccine versus recombinant protein) in rhesus monkeys, necessary for selection of vaccine candidate. Began development of a dengue challenge system. Challenge strains were selected. The Food and Drug Administration (FDA) was consulted and an Investigational New Drug (IND) application was submitted. A challenge protocol was written and submitted for scientific and ethical review. These efforts were necessary for testing and down selection of a dengue candidate vaccine. Developed a neutralization test positive control reference serum with greater dengue type 4 potency, necessary for surveillance and dengue risk assessment among U.S. forces. Demonstrated hyperendemicity (0.1% of children per day) of acute dengue infection among school children in northern Thailand, necessary information for design of clinical vaccine study. Demonstrated high incidence rates of dengue among young persons in Peru, necessary for development of vaccine field testing site. Demonstrated immunogenicity in mice of a combined dengue vaccine using both recombinant protein (maltose binding protein) and a DNA vaccine expressing premembrane and envelope genes, necessary preliminary studies for selection of candidate vaccines for testing in humans. <p>FY 1998 Accomplishments: (continued)</p> <ul style="list-style-type: none"> 860 Demonstrated protection from Russian spring-summer encephalitis (RSSE) and Central European encephalitis (CEE) using a naked DNA vaccine in mice, suggesting that a similar approach may be successful for tick-borne encephalitis (TBE). This is necessary if a replacement for the unlicensed TBE produced in Germany and Austria is to be developed. Began comparative study of immune responses induced by naked DNA vaccines for RSSE and CEE and by the killed TBE virus vaccine produced in Europe, necessary studies for the development of a replacement vaccine for the unlicensed European product. Demonstrated post-exposure prevention of disease due to Ebola virus in mice using two different compounds from the SAH-hydrolase family of compounds, a prelude to further studies in primates to determine potential applicability for human use. Demonstrated high prevalence (89.7%) of West Nile virus infection among Egyptian natives in two villages and documented an infection rate for West Nile virus of 39.5% among 243 U.S. personnel deployed to the Sinai, important components of disease risk assessment. Documented an infection rate of 47.6% among 308 U.S. personnel deployed to the Sinai, an important component for determining operational impact. Developed an ELISA sensitive to both prevalent strains of sandfly fever in Egypt and Jordan, an important component for further assessment of operational risk incurred due to sandfly fever. 530 Documented key epidemiological features of hepatitis E vaccine (HEV) at multiple field sites (China, India, Nepal, Vietnam, Indonesia, Germany, Australia, New Zealand), necessary for future field trials of candidate vaccine. Produced and distributed an enzyme immunoassay (EIA) for HEV screening of 40,000 clinical samples in Thailand and Egypt, necessary for continued sero-epidemiologic studies and risk assessment of HEV. Established purity of candidate vaccine immunogens in mice, rabbits and guinea pigs, necessary for further process development for vaccine production and for IND application. Documented moderately high prevalence of HEV antibody in Vietnam and Indonesia (21% and 11% respectively) and moderately high seroconversion rates after 2 years (5% and 6%, respectively), necessary surveillance for disease risk assessment and potential site development for future vaccine trials. 		

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- 325 Documented human serological evidence of multiple rickettsial diseases [scrub typhus (4%), murine typhus (1%), and spotted fever (1%)] in Indonesia, necessary for disease risk assessment. Identified potential for transfusion-transmitted scrub typhus, important for disease risk assessment; this needs to be further quantified.
- 510 Demonstrated significant anti-leishmanial activity of syringomycin E, a potential new drug for treatment and/or prevention of leishmania infection. Developed and validated a new leishmania culture system for screening of candidate anti-leishmanial drugs. Developed and fielded four new target-based assays for screening of compounds for anti-leishmanial activity, necessary for discovery of new anti-leishmanial drugs. Developed processes for producing excreted antigens from Leishmania promastigotes, necessary for surveillance efforts, use as diagnostic tools, and as potential vaccine immunogens. Began efforts to produce antibodies to excreted antigens for use in development of diagnostic assays; necessary for use as surveillance and diagnostic tools. Established a sandfly infection model for Leishmania, necessary for vaccine development efforts. Established a serum archive for evaluation of potential vaccine immunogens and diagnostic tests. Established a clinical sample collection method for Leishmania, necessary for diagnosis of Leishmania.
- 260 Completed preclinical safety and immunogenicity studies of *N. meningitidis* native outer membrane vesicles (NOMV) for vaccine formulations.
- 880 Reviewed ship logs and documented 10 outbreaks and over 11,000 cases of acute gastroenteritis among sailors aboard 8 aircraft carriers from 1991 to 1994, necessary for determination of disease risk assessment of Norwalk disease and other causes of diarrhea. Documented 4 major outbreaks and the

FY 1998 Accomplishments: (continued)

epidemiology of acute gastroenteritis (principally vomiting) aboard aircraft carriers during FY 1998, necessary for risk assessment. Documented a 29% incidence of seroconversion with antibody to Norwalk virus among 200 randomly selected sailors with diarrhea during a routine deployment that strongly suggests that Norwalk virus is a major cause of acute gastroenteritis among military populations. Developed a model that identifies probable locations of the sandfly which transmits both Leishmania and sandfly fever. Validated the model with sandfly collection at one of the predicted sites, potentially useful in predicting disease risk during deployments. Studied clinical cases of hemorrhagic fevers, encephalitis and hepatitis among pediatric patients in Cambodia; documented that Japanese encephalitis accounted for only 10% of encephalitis among patients, important for understanding and defining new potential risks for encephalitis among deployed U.S. personnel. Documented high rates (83 of 109 patients) of Shigella dysentery among hospitalized patients with bloody diarrhea in Kenya, indicates a significant risk for disease among personnel deployed to Eastern Africa. Documented resistance to Fansidar among 35% of clinical malaria isolates in Kenya. Documented moderately high prevalence of antibodies to multiple Rickettsial diseases (Ehrlichiosis, Q-fever and spotted fever group) in Brazil. Documented reemergence of dengue in Manaus, Brazil (40% of 5,534 clinical samples tested). Established real-time computer surveillance network for infectious disease reporting in eight hospitals in Indonesia. Evaluated a rapid diagnostic test strip in Indonesia for use in field diagnosis of HIV, syphilis and hepatitis B.

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BUDGET ACTIVITY 2 - Applied Research	PE NUMBER AND TITLE 0602787A Medical Technology PROJECT A870	
<ul style="list-style-type: none"> • 1350 Evaluated repellency of three candidate compounds for replacement of DEET, showed equivalency or slightly superior repellent properties of one compound (AI3-37220). Demonstrated efficacy of the lethal ovitrap at reducing dengue vector (<i>Aedes aegypti</i>) populations at 2 sites in Brazil. Demonstrated the ability of the "Combined Wicking" assay for detection of malaria and dengue antigens, potentially useful for far forward detection of infected mosquitoes and risk assessment by deployed forces. Developed PCR primers for detection of all 4 dengue strains in infected mosquitoes, potentially useful for targeting vector control measures to prevent malaria among deployed U.S. personnel. Conducted arthropod surveys in Northern Africa to help prepare field sites for future repellent testing. In vector studies of several species of sandfly, discovered that <i>Phlebotomus sergenti</i> and <i>P. langeroni</i> may be important vectors of <i>Leishmania tropica</i>, necessary to determine optimal vector control measures. • 300 Explored mechanisms of synthesis of bacterial, viral and parasitic antigens, necessary for process and manufacturing development for pilot production of vaccine and other biologics for research and field use. • 11055 Paid administrative overhead costs at the Walter Reed Army Institute of Research (WRAIR). • 9410 Paid transition costs of moving the WRAIR into a new facility. <p>Total 35486</p>	<p>FY 1999 Planned Program:</p> <ul style="list-style-type: none"> • 3190 Complete construction of specially designed amino acid transport proteins (derived from rare codon transfer RNA plasmids) that permit high expression of malaria proteins in the <i>E. coli</i> expression system. Use this system for production of malaria-specific reagents to analyze immune responses to vaccines. Demonstrate feasibility of immunization against <i>Plasmodium vivax</i> using a viral replicon system. • 1050 Express and purify recombinant proteins of at least five different target proteins for structure-based drug design of novel antimalarial drugs. Expand existing capabilities to screen antimalarial drugs by developing new animal models. Analyze the antimalaria activity of novel candidate compounds. Analyze surveillance data and draft a report for Commanders in Chief on the threat of drug-resistant malaria to military operations worldwide, <p>FY 1999 Planned Program: (continued) including recommendations for prophylaxis against malaria and treatment of soldiers with malaria and for monitoring treated soldiers to ensure they have been cured. Develop tests to monitor the development and spread of drug-resistant malaria.</p> <ul style="list-style-type: none"> • 495 Produce purified Shigella vaccine candidate antigens based on the virulence protein epitopes identified in FY 1998. Prepare and submit IND application supporting trials of a live-attenuated <i>Shigella sonnei</i> vaccine. Evaluate the safety and efficacy of combined <i>S. flexneri</i> 2a and <i>S. sonnei</i> vaccine in animal models. • 906 Clone genes encoding three ETEC colonization factor antigens into Good Manufacturing Practice (GMP)-suitable expression vectors for testing as possible vaccine candidates to stimulate protective mucosal antibodies. Characterize human mucosal immune responses to ETEC infection by quantifying serum and luminal antibody responses after ETEC infection in a challenge protocol. Assess role of newly identified ETEC toxins as virulence factors in E. coli-mediated diarrheal disease. 	
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BUDGET ACTIVITY 2 - Applied Research	PE NUMBER AND TITLE 0602787A Medical Technology	PROJECT A870
<ul style="list-style-type: none"> • 864 Determine safety, efficacy and optimal dose schedule of an attenuated live or carrier-based Campylobacter vaccine in animal models. Produce and characterize recombinant Campylobacter proteins identified as a result of FY 1998 6.1 research effort to select those most relevant to protective immunity. Determine feasibility of developing monkey model to assess combined Campylobacter, Shigella and ETEC vaccine efficacy. Determine optimum methods for industrial-scale growth of Campylobacter strains for vaccine production. • 191 Produce malaria and hantavirus diagnostic devices under GMP conditions. Reengineer a Campylobacter diagnostic test and perform initial kit evaluations. Identify appropriate field sites for testing the malaria, Campylobacter and hantavirus diagnostic tests. Integrate specimen collection component into nucleic acid detection platform. • 1531 Evaluate safety and immunogenicity of candidate recombinant, DNA, and killed dengue vaccines in animals. • 793 Evaluate safety of candidate replicon vaccines for Lassa Fever and Congo Crimean Hemorrhagic Fever (CCHF) virus in animals. Develop and validate a rodent model for evaluation of TBE vaccines and therapies. Evaluate safety and immunogenicity of a naked DNA vaccine against TBE in an animal model. Conduct efficacy trial of monoclonal antibody immunotherapy against CCHF and Lassa virus in monkeys. • 649 Determine feasibility of potential components of future diagnostic tests for hepatitis E. Characterize T-cell responses involved in the pathophysiology of HEV. • 396 Clone genes from antibiotic-resistant scrub typhus organisms to develop and define genetic markers and mechanisms of antibiotic resistance. Establish archive of antibody and antigen-positive sera for scrub typhus diagnostic assay development. • 123 Conduct preclinical animal studies with new lots of an outer membrane protein vaccine for prevention of group B meningococcal infection. • 540 Expand disease surveillance worldwide locations and networks and complete threat assessment report concerning any new significant threats of military importance to deployed soldiers. Characterize the new infectious agents and determine if a specific research effort on that agent must be considered. • 1025 Test a method for controlling sand flies in the Middle East by distributing insecticide-treated baits. Clone a drug-resistant strain of <i>Plasmodium vivax</i> malaria in culture. • 91 Explore novel and improved methods of vaccine production and adjuvant research at the Vaccine Pilot Production Facility. <p>FY 1999 Planned Program: (continued)</p> <ul style="list-style-type: none"> • 500 Provide and publish a detailed assessment of the threat of hantaviruses to military operations. Demonstrate efficacy of candidate vaccines in preclinical studies for one or more of the pathogenic Hantaviruses. • 11056 Pay administrative overhead costs at WRAIR. • 403 Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs <p>Total 23803</p> <p>FY 2000 Planned Program:</p>		

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<ul style="list-style-type: none"> • 3713 Develop standardized methodologies including ELISA, proliferative assays, enzyme-linked immunosorbent spot test (ELISPOT) assays, and other methods of reliably measuring immune responses. Conduct preclinical studies of candidate vaccines to support sections 7 (Chemistry, Manufacturing and Control) and 8 (Pharmacology and Toxicology) of an IND application. Develop a method to perform CONUS-based <i>P. vivax</i> sporozoite challenge. Conduct preclinical studies of candidate combined <i>P. falciparum</i> and <i>P. vivax</i> vaccine. • 802 Perform chemical synthesis or isolate from natural products candidate antimalarial drugs. Identify techniques for the cultivation and drug sensitivity testing of vivax malaria. Employ molecular modeling to design antimalarial drugs. Identify, clone, and express target proteins for structure-based drug design and determine modes of action and resistance of antimalarial drugs. Create a deployable field test to assay drug sensitivity patterns in malaria based on enzymatic, colorimetric, probe or micro-array technologies. Conduct target-based and whole organism screening systems for assaying activity or determining cytotoxicity candidate drugs. Conduct assays to discover synergistic drug combinations or resistance modulator drugs. Create computer systems to analyze, merge, and compare physicochemical and biological data. Maintain a drug repository to include acquisition, storage and distribution. Prepare radiolabeled drug candidates for preclinical studies of drug distribution, pharmacokinetic and metabolism. Prepare gram and kilogram quantities of drug candidates under Good Laboratory Practice (GLP)/GMP. Perform preclinical toxicology studies of new drugs. Prepare drug delivery systems of compounds under GLP/GMP. Conduct a surveillance program for drug-sensitivity patterns of malaria from diverse geographic regions. • 670 Modify candidate live vaccines to reduce reactogenicity and/or excretion while retaining efficacy. Modify candidate live vaccines to support rapid identification of excreted organisms. Modify candidate vaccines to enhance efficacy. Devise polyvalent vaccines using live <i>Shigella</i> carrier(s) or subcellular protein carrier(s). • 787 Determine and characterize relevant ETEC virulence factors. Develop expression vectors for relevant ETEC antigens. Enhance mucosal immune responses by microencapsulation and adjuvant technologies. Develop an improved animal model for ETEC infection. Develop a multivalent vaccine to include protection against enteric pathogens in addition to ETEC. Improve methods to diagnose ETEC infections. • 759 Explore new and/or improved animal models of <i>Campylobacter enteritis</i> and immunity, including the ferret, the pig, and nonhuman primates. Develop improved diagnostics utilizing either antigen detection or nucleic acid based tests. • 138 Develop infectious disease-specific reagents for a portable device capable of detecting and identifying nucleic acids by integrating four separate processes: specimen processing, amplification of gene targets, detection of product or signal, and simplified data analysis. Devise specimen processing methods that allow the purification of target nucleic acids in less than 30 minutes. Develop reagents for malaria, enteric diseases, dengue viruses, and the hemorrhagic fever viruses. Identify unique gene amplification primers and probes. Identify multiple gene targets per agent. <p>FY 2000 Planned Program: (continued)</p> <ul style="list-style-type: none"> • 1702 Ascertain whether immunity to premembrane envelope protein generated by “dead” or DNA vaccine is a sufficient basis for immunization of humans of diverse genetic backgrounds. Validate measures of T-cell memory and assess their relevance to immunity against disease. Validate a method for quantitation of “enhancing” antibodies. Characterize the host and virus determinants of severe dengue disease (plasma leakage, hemorrhage, liver injury, central nervous system injury). Determine the feasibility of second generation live vaccines (engineered attenuation, made from infectious clones, higher yield cell substrate, etc.). 		

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<ul style="list-style-type: none"> • 675 Assess mechanisms of pathogenesis to include viral-specific events and non-specific factors including cytokines and coagulation factors in animal models of viral hemorrhagic fever (VHF) and encephalitis. Develop candidate vaccines for VHF and encephalitis agents in appropriate animal models. Evaluate antiviral drug candidates for efficacy in vitro and in animal models. Develop and evaluate primate monoclonal antibodies for protective efficacy in animal models including primates. Improve capability to rapidly identify these agents in the field and to provide definitive confirmation in reference labs. • 430 Establish level of antibody that prevents disease. Refine characterization of human T-cell responses to HEV infection, disease, and vaccine. Refine epidemiology of HEV and virus phylogenetic analysis in Asia and Africa. Sustain or refute presence of hepatitis E disease among humans in Latin America using virus detection as basis for diagnosis. Characterize animal reservoir (particularly rodents) and animal HEV isolates. • 479 Establish the degree of immunologic heterogeneity among available <i>Orientia</i> isolates. Define a set of <i>Orientia</i> isolates that exhibit little or no cross-protection against heterologous challenge in mice. Clone and sequence appropriate strain-specific antigens from appropriate noncross-protective isolates for use in the development of a polyvalent scrub typhus vaccine. Characterize, maintain and use a scrub typhus-infected chigger colony to evaluate scrub typhus vaccines for use as a challenge in a mouse or primate protection model. • 100 Identify and genetically modify candidate vaccine strains to maximize expression of desirable antigens and minimize expression of undesirable antigens. Complete animal immunogenicity and safety studies to determine the optimal parameters for use in vaccine production, presentation, and formulation. Conduct a detailed serological analysis of the animal and human immune responses to the vaccines to determine which antigens are the most immunogenic, and to determine the capacity of induced antibodies to kill group B strains of different subtypes. Determine the importance of the iron uptake proteins and the Opc outer membrane protein (OMP) in the vaccines by analysis of the antibody response of animals and humans. Identify and genetically modify additional vaccine strains representing other prevalent OMP subtypes and lipooligosaccharide (LOS) immunotypes. The immunogenicity of these additional vaccine strains should be determined in animals. • 35 Conduct surveillance to identify emerging pathogens that place deployed soldiers at risk for febrile illnesses, respiratory disease, encephalitis, diarrhea, hemorrhagic fever and other conditions. • 926 Establish a standard insecticide resistance and susceptibility test at each laboratory, choose a group of local vectors to be tested each year (to include <i>Aedes aegypti</i>, where available), and perform trial tests. Evaluate the threat of tick and chigger-borne diseases to the U.S. military. Begin development of a dengue vector control system, an integrated system of tools and information that can be physically packaged for a Preventive Medicine Detachment (or service equivalent): (1) perform thorough evaluation of components necessary for the system, including those which remain to be developed; (2) prepare a trial device for evaluating pools of vectors for presence of virus; and (3) establish basic research on new devices for evaluating biting rate and distribution of vectors. Conduct preliminary development of devices and techniques that may serve as components of a vector control system for malaria vectors, including a field device for detecting <i>Plasmodium</i> in vectors. <p>FY 2000 Planned Program: (continued)</p> <ul style="list-style-type: none"> • 1112 Devise processes for manufacture of at least 10 new vaccine lots under cGMP compliance. 		

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<ul style="list-style-type: none"> • 410 Develop and test in animals a candidate vaccine to one or more hantaviruses, assessing immune responses and protection. Improve capability to rapidly identify, assess risk, and formulate control strategies for hantaviruses, including: (1) developing new techniques to detect hantaviruses; (2) evaluating therapeutic reagents (e.g., human monoclonal antibodies, or antivirals) for hantaviruses and test in cell culture and animals; (3) isolating and characterizing novel hantaviruses. • 11056 Pay administrative overhead costs at WRAIR. <p>Total 23794</p> <p>FY 2001 Planned Program:</p> <ul style="list-style-type: none"> • 4028 Express proteins encoded by the <i>P. vivax</i> gene homologs of the <i>P. falciparum</i> candidate vaccine components. Test their immunogenicity in an animal model. Develop field sites for <i>P. vivax</i> human vaccine trials. • 1576 Develop a field site for testing a drug for treatment of multidrug-resistant malaria. • 712 Complete animal trials of candidate <i>S. dysenteriae</i> vaccines. Characterize proteins identified through genomic sequence data analysis to verify their possible application to vaccine development. Construct candidate polyvalent Shigella vaccines and screen for immunogenicity in an animal model. • 897 Characterize the optimal formulation of the ETEC components of the combined enteric vaccine. Prepare field sites for the evaluation of the candidate ETEC microencapsulated vaccine. • 784 Characterize the immune responses associated with recovery from Campylobacter infection and subsequent protection. • 231 Design an automatic reporting system that can detect positive agent identification within 30 minutes, for the nucleic acid identification platform. Transition the malaria and dengue nucleic acid primers and probes onto the nucleic acid identification platform. • 1841 Develop a cytotoxic T-cell technology to evaluate dengue vaccine candidates. • 624 Design generic hemorrhagic fever intervention strategies to interrupt vascular endothelial cell infection and ultimate hemorrhage, applying results of preceding 6.1/6.2 pathogenesis studies. • 363 Assess the threat of hepatitis E to U.S. service members in Africa and Latin America. • 420 Demonstrate the feasibility of immunologic protection against scrub typhus in an animal model and demonstrate efficacy of a candidate scrub typhus vaccine in an animal model. • 534 Genetically alter the antigenic composition of a group B meningococcal candidate vaccine strain to enhance the ability to propagate it. • 171 Identify vertebrate hosts for hemorrhagic viruses determined to pose a threat to U.S. service members. • 640 Develop a rapid immunological method for detecting Leishmania infected sand flies. Test a synthetic replacement for the insect repellent DEET. Determine a strategy to render the <i>P. falciparum</i> multidrug-resistant gene ineffective. • 781 Develop an improved ferret animal model to assess LTR192G-adjuvanted enteric vaccines, to increase predictive ability of side effects in human clinical studies. <p>FY 2001 Planned Program: (continued)</p> <ul style="list-style-type: none"> • 246 Transition to advanced development a multivalent Hantavirus vaccine to prevent infection with viruses causing hemorrhagic fever with renal syndrome (HFRS) or hantavirus pulmonary syndrome in immunized personnel. 		
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BUDGET ACTIVITY
2 - Applied Research

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• 11056 Pay administrative overhead costs at WRAIR.
Total 24904

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BUDGET ACTIVITY 2 - Applied Research	PE NUMBER AND TITLE 0602787A Medical Technology	PROJECT A872
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COST (<i>In Thousands</i>)	FY1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY2004 Estimate	FY2005 Estimate	Cost to Complete	Total Cost
A872 Neurofibromatosis Research	9180	11425	0	0	0	0	0	0	0	20605

Mission Description and Justification: By Congressional direction, the purpose of this project is to develop research models for neurofibromatosis.

FY 1998 Accomplishments:

- 9180 Published a Program Announcement in May 1998. Conduct scientific peer review and programmatic review by April 1999. Initial awards will be made in May 1999, with all awards completed no later than 30 September 1999.

Total 9180

FY 1999 Planned Program:

- 11123 Publish a Program Announcement in May 1999. Conduct scientific peer review and programmatic review by December 1999. Initial awards will be made in January 2000, with all awards completed no later than 30 September 2000.
- 302 Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs

Total 11425

FY 2000 Planned Program: Project not funded in FY 2000.

FY 2001 Planned Program: Project not funded in FY 2001.

Project A872

DATE
February 1999

BUDGET ACTIVITY
2 - Applied Research

PE NUMBER AND TITLE
0602787A Medical Technology

COST (In Thousands)	FY1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY2004 Estimate	FY2005 Estimate	Cost to Complete	Total Cost
D873 HIV Exploratory Research	20414	14548	12634	11648	11095	10976	11473	11699	Continuing	Continuing

Mission Description and Justification: This project provides for 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. Current policy prohibits antibody positive service members from deployment outside the continental United States. A safe and effective vaccine for prevention of infection and intervention techniques will permit all service members to become worldwide-deployable.

FY 1998 Accomplishments:

- 18694 Demonstrated induction of neutralizing antibody against heterologous viral isolates and protection from challenge with heterologous viral isolates of HIV in rhesus macaque monkeys using a candidate vaccine consisting of oligomeric glycoprotein 140 (ogp140), administered in high and low dosages. Demonstrated immunogenicity and lack of virulence with 2 *nef*-deleted (attenuated), live simian immunodeficiency virus (SIV) vaccines in pig-tailed and rhesus macaques, a necessary step in the development of candidate live-virus vaccines to prevent HIV infection. One of the attenuated viruses protected immunized macaques from persistent infection after challenge. In a monkey model, demonstrated immunogenicity of a combined DNA (*env* & *rev*) + oligomeric gp160 (ogp160). Using the same DNA + ogp160 vaccine, also demonstrated protection from a lab-adapted strain of simian/human immunodeficiency virus hybrid (SHIV) vaccine but not from a "primary" SHIV isolate (a virus containing an HIV envelope component derived directly from a patient isolate and not adapted to laboratory culture). Demonstrated the ability to infect a monkey model with vaginally inoculated pathogenic SHIV, necessary for animal challenge studies of candidate vaccine constructs. Demonstrated that vaccine adjuvants (co-substances given with vaccines to enhance induction of immune response) can alter the specificity of the vaccine induced immune response, important to designing, developing and administering adjuvant systems for HIV vaccines. Demonstrated that the recombinant ogp140 does not induce an antibody immune response which is identical to natural infection, important for designing immunogenic and protective vaccines for the prevention of HIV infection. Demonstrated preferential binding of native HIV antigens by vaccine antibodies induced by vaccine from primary isolate as opposed to lab adapted isolates, important in choosing sources of vaccine immunogens. Demonstrated greater cross-strain recognition of conformational epitopes by antibodies induced using a primary virus isolate as a source for vaccine immunogen, important for choosing the source for vaccine immunogens. Demonstrated that the proclivity of vaccine induced antibodies to bind to viral antigens increases with time; this may be important for understanding design and administration requirements for candidate vaccines. Demonstrated immunogenicity of intratracheally administered SHIV vaccine in rhesus macaques. In the same experiment, demonstrated little or no protection from vaginal challenge of vaccinated monkeys and obtained data that suggested a role for IgA as a necessary component for protection from mucosal transmission of retroviral infection, similar to studies

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<p>conducted by DoD scientists in highly-exposed, persistently seronegative (HEPS) prostitutes in Thailand. These studies are important preliminary studies for understanding vaccine design and administration requirements for protection from mucosal (sexual) transmission of retroviral infection.</p> <p>FY 1998 Accomplishments: (continued)</p> <p>Began first clinical study of a DNA vaccine candidate for protection from HIV infection, study ongoing. In the Thai HEPS cohort, produced data which suggest that locally produced IgA antibody to gp160 in the vaginal mucosa may play a role or be a marker for protection from sexual transmission of HIV, important for understanding factors related to design and administration of a protective HIV vaccine. In the Thai HEPS cohort, demonstrated a higher prevalence of HLA-B18, similar to studies of sex-workers in Kenya and similar to results in rhesus macaques (see above), important for understanding immune factors that would be necessary for protection from HIV infection. Demonstrated a potential relationship between the levels of two specific HIV antibodies [serum binding IgA antibody to subtype E gp120 and serum IgG antibody to subtype B peptide (832)] in maternal serum and transmission of HIV infection to neonate, important for understanding immunological requirements for protection from HIV infection. Demonstrated no relationship between maternal levels of autologous neutralizing antibody to HIV and subsequent maternal-infant transmission, important for understanding immunological correlates of protection from HIV infection. Demonstrated correlation of maternal cervical viral burden with plasma viral burden and with subsequent maternal-infant transmission of HIV infection, important for understanding virological correlates of protection from HIV infection. Demonstrated that anti-HIV-1 neutralizing antibodies block HIV infection of key cells of the immune system and therefore that vaccine-induced neutralizing antibody is an important component of an effective vaccine. Established key laboratory technologies, methodologies, processes and capabilities at laboratories in Thailand, necessary for ensuring the proper collection, processing and assaying of clinical samples obtained as part of future clinical vaccine studies. Demonstrated significantly greater natural killer (NK) cell functional activity among Thai subjects compared to North American subjects, data will be confirmed by additional studies in North America, necessary for understanding host immunological factors in the design of candidate vaccines. Demonstrated that samples for cytotoxic T lymphocyte (CTL) study may be cryopreserved after in vitro stimulation with no essential loss in assay sensitivity, important for preparing and standardizing laboratory and specimen handling processes and methodologies and for simplifying laboratory requirements for remotely obtained clinical samples for complex assays. Using antibody mapping techniques, developed improved understanding and techniques for characterizing the immune responses in humans and animals receiving candidate vaccines, necessary for studying vaccine immunogenicity and host response in the development of protective HIV vaccines. Conducted HIV surveillance and risk assessment in North Africa, the Middle East, Eastern Europe and South Asia, necessary for ongoing epidemiological studies and risk assessment for U.S. forces. Established HIV genotyping capabilities in Egypt as part of ongoing HIV molecular epidemiological studies.</p> <ul style="list-style-type: none"> • 1720 Paid administrative overhead costs at the Walter Reed Army Institute of Research (WRAIR). <p>Total 20414</p> <p>FY 1999 Planned Program:</p>		
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<ul style="list-style-type: none"> • 12453 Conduct preclinical studies of clade B oligomeric protein vaccine candidates. Establish domestic laboratory infrastructure for support of vaccine efficacy trials. Study the molecular conformation of vaccine proteins and the effects of vaccine adjuvants. Study viral correlates of HIV transmission and pathogenesis. Characterize HIV-specific protective epitopes of vaccine products for National and International use. • 1720 Paid administrative overhead costs at WRAIR. 375 Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs 		
Total	14548	
FY 2000 Planned Program:		
<ul style="list-style-type: none"> • 10914 Evaluate the importance of HIV genotypes in predicting HIV immunotypes necessary for inclusion in an HIV vaccine. Define the correlates of immunity to HIV, necessary for vaccine design. Establish genetic and phenotypic correlates of drug resistance among HIV-1 clinical isolates, necessary for establishing drug treatment strategies for military dependents. Conduct animal studies of candidate HIV vaccines to prevent HIV infection. Evaluate and validate a rapid test for field diagnosis of HIV infection. Evaluate the importance of HIV genotypes in predicting HIV immunotypes necessary for inclusion in an HIV vaccine. Define the correlates of immunity to HIV. 1720 Paid administrative overhead costs at WRAIR. 		
Total	12634	
FY 2001 Planned Program:		
<ul style="list-style-type: none"> • 9928 Clinical validation of novel diagnostic and prognostic measurements of HIV-1 virological markers. Preclinical studies of multi-clade oligomeric vaccine candidates. 1720 Pay administrative overhead costs at WRAIR. 		
Total	11648	

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BUDGET ACTIVITY 2 - Applied Research				PE NUMBER AND TITLE 0602787A Medical Technology				PROJECT A874			
COST (<i>In Thousands</i>)		FY1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY2004 Estimate	FY2005 Estimate	Cost to Complete	Total Cost
A874 Combat Casualty Care Technology		8364	10403	8580	8827	9102	9429	9896	10440	Continuing	Continuing

Mission Description and Justification: 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. This project addresses investigation of the treatments for weapons-induced trauma and burns, and shock due to blood loss. It also funds technologies for resuscitation fluid and blood preservation.

FY 1998 Accomplishments:

- 100 Developed specifications for a miniature version of the Critical Care System for Trauma and Transport (CSTAT) - the miniSTAT - as a far-forward intensive care and diagnostic support platform.
 - 400 Refined sensors and surgical and evaluation technologies, including the CSTAT, for far-forward diagnosis and treatment of casualties.
 - 400 Compared early versus delayed fluid resuscitation following massive hemorrhage associated with penetrating trauma to develop optimal resuscitation protocols.
 - 75 Developed animal model and completed pilot studies of freeze-dried vascular allografts for far-forward surgical replacement of damaged blood vessels.
 - 700 Determined performance-based standards for red blood cell storage to enhance availability of red blood cells far forward.
 - 900 Identified channel blockers and proteosome inhibitors with neuroprotective attributes to reduce the morbidity and mortality following head injuries.
 - 100 Evaluated effectiveness of silver-coated pins for far-forward fracture fixation and stabilization.
 - 200 Began evaluation of a fibrin foam-based hemostatic agent designed to reduce blood loss from penetrating wounds.
 - 300 Investigated treatments for smoke inhalation injuries.
 - 300 Continued development of monitoring and treatment protocols to address infection in burn wounds.
 - 450 Evaluated fibrin-based bandage as a hemostatic treatment for organ lacerations.
 - 400 Investigated platelet and plasma preservative technologies to enhance availability of these blood products far forward.
 - 350 Evaluated the induction of trauma-associated coagulopathy as a risk factor for bleeding disorders.
 - 500 Examined dermal replacement methods for repair of burned skin.
 - 422 Investigated treatments for burns.
 - 250 Identified cytokine mRNA expression in hemorrhage models to identify possible targets for therapy against shock.
 - 2517 Funded general and administrative expenses for the Institute of Surgical Research.
- Total 8364

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FY 1999 Planned Program:		
<ul style="list-style-type: none"> • 300 • 2000 • 1000 • 300 • 200 • 200 • 300 • 478 • 1500 • 150 • 150 • 150 • 100 • 350 • 500 • 1556 • 960 • 208 Total 	<ul style="list-style-type: none"> Continue development of the miniSTAT as a far-forward intensive care and diagnostic support platform. Plus up for the Life Support for Trauma and Transport (LSTAT). Investigate methods for the prevention of ischemia/reperfusion injury in brain, spinal cord, and other organs. Investigate microencapsulated antibiotics and oral plaque reducing agents. Evaluate methods to treat tension pneumothoraces. Evaluate topical anti-infective agents. Evaluate treatments for smoke and thermal inhalation injuries. Conduct evaluations of wound and injury repair techniques to correct battle or training injuries. Continued research into the treatment of burns. Begin evaluation of techniques for the formulation and assessment of efficacy and safety of dried plasma products. Continue development of methods to extend platelet shelf life. Begin development of medical surgical devices to simplify treatment of trauma. Investigate advanced field anesthesia. Begin formulation of storage solution for 10-week storage of red blood cells. Continue testing of fibrin bandage and foam-based hemostatic agents. Fund general and administrative expenses for the Institute of Surgical Research. Establish Congressionally earmarked program to study pain research. Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs 	
FY 2000 Planned Program:		
<ul style="list-style-type: none"> • 100 • 1000 • 300 • 200 • 200 • 300 • 480 • 500 • 150 	<ul style="list-style-type: none"> Complete development of the miniSTAT as a far-forward intensive care and diagnostic support platform. Select lead drugs for testing in in-vivo models of ischemia/reperfusion injury in brain, spinal cord, and other organs. Investigate microencapsulated antibiotics and oral placque reducing agents to be used in the field. Complete evaluation of methods to treat tension pneumothoraces. Evaluate topical anti-infective agents. Evaluate treatments for smoke and thermal inhalation injuries. Conduct evaluations of wound and injury repair techniques to correct battle or training injuries. Continue research into the treatment of burns. Begin evaluation of techniques for the formulation and assessment of efficacy and safety of dried plasma products. 	
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BUDGET ACTIVITY 2 - Applied Research	PE NUMBER AND TITLE 0602787A Medical Technology	PROJECT A874
<p>FY 2000 Planned Program: (continued)</p> <ul style="list-style-type: none"> • 150 Continue development of methods to extend platelet shelf life to enhance availability far forward. • 800 Evaluate optimal hemorrhage resuscitation protocols to be used by first responders. • 150 Continue development of medical surgical devices to simplify treatment of trauma in austere environments. • 100 Continue to investigate advanced field anesthesia. • 350 Complete formulation of storage solution for 10-week storage of red blood cells. • 1000 Continue testing of fibrin foam-based hemostatic agent. • 200 Complete testing of fibrin bandage-based hemostatic agent. • 2600 Fund general and administrative expenses for the Institute of Surgical Research. <p>Total 8580</p> <p>FY 2001 Planned Program:</p> <ul style="list-style-type: none"> • 100 Test miniature version of the miniSTAT as a far-forward intensive care and diagnostic support platform. • 1000 Continue development of in vivo models of ischemia/reperfusion injury in brain, spinal cord, and other organs. • 500 Investigate microencapsulated anesthetics/analgesics as agents to allow more rapid return to duty. • 200 Complete evaluations of topical anti-infective agents. • 300 Continue to evaluate treatments for smoke and thermal inhalation injuries. • 365 Conduct evaluations of wound and injury repair techniques to correct battle or training injuries. • 500 Continue research into the treatment of burns. • 200 Continue evaluation of techniques for the formulation and assessment of efficacy and safety of dried plasma products to replace frozen product. • 200 Continue development of methods to extend platelet shelf life to enhance the availability of platelets far forward. • 400 Evaluate nonfibrin-based hemostatic dressings. • 500 Investigate the diagnosis and treatment of blunt trauma injuries. • 300 Continue development of medical surgical devices to simplify treatment of trauma in austere environments. • 350 Complete testing of storage solution for 10-week storage of red blood cells. • 1000 Continue testing of fibrin foam-based hemostatic agent. • 200 Complete testing of fibrin bandage-based hemostatic agent. • 2712 Fund general and administrative expenses, Institute of Surgical Research. <p>Total 8827</p>		
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BUDGET ACTIVITY 2 - Applied Research	PE NUMBER AND TITLE 0602787A Medical Technology	PROJECT A878
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COST (In Thousands)	FY1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY2004 Estimate	FY2005 Estimate	Cost to Complete	Total Cost
A878 Health Hazards of Military Materiel	7506	8671	9322	9684	9931	10240	10826	11395	Continuing	Continuing

Mission Description and Justification: This project focuses on protecting soldiers from health hazards associated with their own materiel and operational environments. Emphasis is on identification of health hazards inherent to the engineering design and operational use of equipment, systems and materiel used in Army combat operations and training. Specific hazards include repeated impact/jolt and vibration stress from the operation of combat vehicles and aircraft; blast overpressure and impulse noise generated by firing weapons systems; toxic chemical hazards associated with deployment into environments contaminated with industrial waste and agricultural chemicals; non-ionizing radiation directed energy sources (laser); and environmental stressors (e.g., heat, cold, terrestrial altitude). Specific medical 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.

FY 1998 Accomplishments:

- 500 Showed efficacy of a particle cell switch inserted in a tank sight to provide protection against visible and infrared battlefield lasers.
- 500 Showed that conventional glucocorticoid therapy for laser-induced retinal injury was ineffective in minimizing retinal inflammation and scar formation.
- 700 Identified efficacy of a candidate drug to treat laser-induced eye injury by minimizing acute leukocyte intrusion and reducing long-term retinal scar formation.
- 475 Developed model to evaluate exposure to repeated impacts in military vehicles.
- 950 Compiled all blast overpressure human and animal data collected over the past decade of U.S. Army Medical Research and Materiel Command (USAMRMC) research and derived preliminary estimates of free field impulse noise exposure limits.
- 558 Developed a preliminary whole-body injury model to predict injury to head, thorax, and abdomen, penetration of skin, and lethality.
- 319 Determined that moderate dehydration does not impair temperature regulation during short-duration whole-body cold exposures.
- 221 Determined that hyperhydration does not improve cardiovascular stability or tolerance to uncompensable heat stress.
- 600 Demonstrated successful field application of automated fish biomonitoring system for detecting Pfiesteria-like neurotoxin in water.
- 500 Demonstrated efficacy of flumazenil, a benzodiazepine antagonist, in reversing sleep inertia upon awakening.
- 683 Identified individual and unit factors associated with sexual harassment for report to senior Army leadership.
- 1200 Developed and validated metrics for assessing aviation crew coordination, psychological stress, and thermal stress of the aviator nuclear, biological and chemical (NBC) ensemble.
- 300 Demonstrated efficacy of physiological status monitoring on international climb of Mt. Sanford, Alaska.

Total 7506

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ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)		DATE February 1999
BUDGET ACTIVITY 2 - Applied Research	PE NUMBER AND TITLE 0602787A Medical Technology	PROJECT A878
FY 1999 Planned Program:		
• 750	Field a Laser Accident and Incident Register as a relational database and accompanying expert system for use in Army Medical Department (AMEDD) training, triage and treatment.	
• 750	Assess the advanced laser protection requirements for the soldier through employment of animal and human tracking performance models.	
• 900	Develop head-supported mass model based on fatigue criteria for female aviators and reevaluate existing neck injury tolerance thresholds and injury mechanisms.	
• 850	Define injury thresholds for acceleration and impact in military vehicles.	
• 950	Validate reliable measurements to assess blunt trauma (nonlethal kinetic projectiles, behind body armor trauma, etc.) for evaluation of protective value of body armor for which no validated standard exists.	
• 600	Refine predictive model of toxic combustion gas incapacitation with incorporation of results from halon fire-suppressant alternatives and injury biomarker studies.	
• 918	Develop near real-time animal sentinels/monitors for classes of chemicals with common modes of hazard to human health.	
• 930	Develop rapid methods to detect low levels of fecal coliform bacteria contamination in field water and food.	
• 350	Determine if repeated exposure or exercise in the cold alters vasoconstriction and extremity temperatures.	
• 1118	Develop the aviation crew coordination evaluation system and apply to assessment of auditory performance in rotary-wing aviation.	
• 375	Revise and validate U.S. Army Fluid Replacement Guidelines for Hot Weather Training.	
• 180	Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs	
Total	8671	
FY 2000 Planned Program:		
• 921	Design field therapy packs for treatment of laser-induced eye injury.	
• 883	Validate blunt trauma measurements and the pathology induced by blunt trauma produced by nonlethal projectiles and behind body armor based on cadaver and other studies.	
• 821	Update the crew casualty-soldier survivability predictive model of incapacitation with particulate-heat results and integrate the model with nongas models of incapacitation.	
• 883	Define operational environments for head-supported mass and correlate to neck injury.	
• 571	Develop a new injury prediction model for impulse noise exposure that can be used to assess hearing protection.	
• 421	Assess potential therapeutics against blast-induced neuronal damage.	
• 871	Determine feasibility of a near real-time monitor for analyzing oxidant stress effects in humans from environmental stressors and toxic chemical exposures.	
• 821	Determine feasibility of a real-time assay for toxic industrial and agricultural chemical contamination of field water and food.	
• 446	Evaluate and quantify the efficacy of anti-cytokines as pretreatments or treatment to heat injury and illness.	
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BUDGET ACTIVITY 2 - Applied Research	PE NUMBER AND TITLE 0602787A Medical Technology	PROJECT A878
<ul style="list-style-type: none"> • 421 Measure the effects of prior activity on body heat balance during subsequent cold exposure. 		
<p>FY 2000 Planned Program: (continued)</p>		
<ul style="list-style-type: none"> • 1139 Conduct studies of pharmacological (temazepam, zolpidem) and nonpharmacological (bright lights, melatonin) countermeasures to sustain mental performance during night work and deployments across time zones. 		
<ul style="list-style-type: none"> • 749 Evaluate individual and unit factors predisposing soldiers to development of persistent nonspecific symptoms common to many Gulf War veterans. 		
<ul style="list-style-type: none"> • 375 Determine effects of intermittent exercise on physiologic tolerance to uncompensable heat stress. 		
<p>Total 9322</p>		
<p>FY 2001 Planned Program:</p>		
<ul style="list-style-type: none"> • 411 Develop crew casualty-soldier survivability predictive model of incapacitation with particulate and heat factors to integrate with nongas models of incapacitation. 		
<ul style="list-style-type: none"> • 900 Integrate models of concussive head injury, head and spine, and head-supported mass tolerance limits into a generic and comprehensive performance and injury model of forces to head and neck region. 		
<ul style="list-style-type: none"> • 1000 Complete exploratory development of validated injury prediction model for impulse noise to replace current Military Standard 1474C for impulse noise exposure. 		
<ul style="list-style-type: none"> • 700 Quantify the effects of oral contraceptives on immune modulators and physiological responses to exercise in the heat in females. 		
<ul style="list-style-type: none"> • 700 Develop recommended standards for materiel developers on inertial loads and helmet dynamic retention. 		
<ul style="list-style-type: none"> • 1400 Complete exploratory development of validated head-supported mass model for prediction of injury and performance decrements associated with helmet mounted equipment. 		
<ul style="list-style-type: none"> • 1350 Design field therapy packs for treatment of laser-induced eye injury. 		
<ul style="list-style-type: none"> • 1778 Complete exploratory development of noninvasive stress diagnostics based on sweat and saliva analyses of neurochemical metabolites to predict impending stress casualties. 		
<ul style="list-style-type: none"> • 1351 Complete exploratory development of near-real time bioassay detector and personal exposure monitor for neurotoxic industrial and agricultural chemicals. 		
<ul style="list-style-type: none"> • 94 Demonstrate effects of muscle injury and inflammation response on thermoregulation and susceptibility to heat injury. 		
<p>Total 9684</p>		
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BUDGET ACTIVITY 2 - Applied Research	PE NUMBER AND TITLE 0602787A Medical Technology	PROJECT A879
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COST (<i>In Thousands</i>)	FY1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY2004 Estimate	FY2005 Estimate	Cost to Complete	Total Cost
A879 Medical Factors Enhancing Soldier Effectiveness	10530	7960	8054	8456	8760	9093	9446	9975	Continuing	Continuing

Mission Description and Justification: This project focuses on sustaining warfighting capability by 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.

FY 1998 Accomplishments:

- 623 Determined that creatine monohydrate supplementation increased strength endurance by 15% in elite soldiers.
 - 820 Determined dehydration reduces skeletal muscle endurance but has no effect on muscle metabolism.
 - 375 Determined that oral glycerol administration is not effective in preventing acute mountain sickness.
 - 625 Developed a database of the physically demanding tasks performed by soldiers for all Army military occupational specialties.
 - 1275 Developed reliable cold stress simulations with consolidation of two mathematical models with biophysics properties into MERCURY.
 - 663 Delineated role of exertional fatigue, sleep loss and negative energy balance on risk of hypothermia in Ranger students.
 - 700 Completed exploratory demonstration of the efficacy of repeated 10-mg doses of amphetamine in sustainment of aviator performance during 64-hour period of sleep deprivation.
 - 607 Completed exploratory demonstration of the feasibility of predicting performance on the basis of prior sleep history and circadian phase useful for a sleep/performance model that can be installed in a wrist-worn actigraph device.
 - 642 Developed approach to operational stress assessment combining measures of morale, leadership, unit cohesion, sleep, and psychological stress.
 - 400 Completed exploratory demonstration of the practical applications of physiological status monitoring (core temperature, global positioning system (GPS) velocity and location, locomotory energy expenditure, heart rate) during small unit operations in a concept evaluation phase (CEP) with the Dismounted Battlespace Battlelab.
 - 600 Developed contrast image quality figures of merit for flat panel displays.
 - 3200 Conducted Congressionally mandated program of nutrition research support including military field studies at Marine Corps basic recruit training, bone metabolism in weightless environments, and field assessments of the adequacy of operational rations.
- Total 10530

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ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)		DATE February 1999
BUDGET ACTIVITY 2 - Applied Research	PE NUMBER AND TITLE 0602787A Medical Technology	PROJECT A879
FY 1999 Planned Program:		
•	600 Develop and apply battery of psychoneurophysiological tests to measure stress status baseline in rapid deployment forces for comparison during and after future deployments.	
•	750 Study morale, leadership, unit cohesion, sleep and psychological stress correlates of performance in Ranger and Special Operations Forces training courses and/or exercises at the National Training Center.	
•	625 Determine the physical fitness of soldiers entering and completing basic combat training and its role in injury incidence.	
•	669 Identify health outcomes, health habits, and risk behavior of enlisted soldiers in the 25 most common military occupational specialties.	
•	500 Evaluate feasibility of chronic tyrosine supplementation to sustain mental performance in high-stress environments.	
•	168 Evaluate the effects of oxygenated perfluorocarbons for their ability to rewarm from hypothermia and reduce the pathophysiological effects of hypothermia/rewarming in a miniswine model.	
•	665 Determine if the thermoregulatory system “fatigues” when multiple cold exposures are repeated with minimal recovery time between exposures.	
•	694 Determine if changes in intraocular pressure, hypoxic ventilatory depression or speech pattern during altitude exposure are predictive of acute mountain sickness.	
•	1275 Develop and refine integration of SCENARIO model into MERCURY for reliable prediction of physiological responses to heat and cold stress applicable in training and operations for both mounted and dismounted soldiers.	
•	700 Study the effects of Modafinil during 64 hours of sleep deprivation, as a potential nonamphetamine intervention to sustain aviator performance.	
•	600 Compare effectiveness of Modafinil with caffeine for sustaining performance with sleep deprivation in continuous operations.	
•	600 Develop spatial-temporal techniques for assessing dynamic capabilities of panel-mounted and helmet-mounted displays.	
•	114 Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs	
Total	7960	
FY 2000 Planned Program:		
•	755 Evaluate the ability of anti-freeze proteins to protect isolated human blood mononuclear cells from hypoxia and exposure to extreme cold stress.	
•	767 Document the effect of moderate altitude residence on oxygen saturations in soldiers acutely exposed to altitudes from 6,000 to 14,000 ft.	
•	1302 Develop a neural network model of cardiovascular response including human fluid compartments and refine the model for accurate prediction of injuries caused by water imbalances.	
•	750 Define optimal dosage and timing of caffeine to sustain or enhance cognitive and psychomotor performance during continuous operation scenarios involving 48-72 hours of sleep deprivation.	
•	800 Study flight performance effects of various candidate drug interventions during 64 hours of sleep deprivation.	
•	700 Develop advanced sleep scoring algorithm and sleep/performance model for integration into the advanced version of the sleep watch actigraph.	
•	700 Refine techniques to assess dynamic capabilities of panel-mounted and helmet-mounted displays in relation to spatial and temporal limitations of the human user in aviation environments.	
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BUDGET ACTIVITY 2 - Applied Research	PE NUMBER AND TITLE 0602787A Medical Technology	PROJECT A879
<p>FY 2000 Planned Program: (continued)</p> <ul style="list-style-type: none"> • 755 Complete exploratory demonstration of the efficacy of short-term use of “fat antabuse” drug (Xenacal) to provide beneficial and lasting modification of health habits of moderately overweight soldiers. • 705 Conduct systematic studies to develop training recommendations to improve basic combat training physical fitness programs to optimize military performance and reduce training injuries. • 820 Determine efficacy of local vasodilators in maximizing regional dry heat loss. <p>Total 8054</p> <p>FY 2001 Planned Program:</p> <ul style="list-style-type: none"> • 368 Develop health promotion and behavioral strategies to improve soldier health habits and military readiness in deployment. • 600 Evaluate the effects of physical fatigue, sleep deprivation, and other operational stressors on the pathophysiological responses to acute or chronic cold exposure. • 700 Quantify the role of liposaccharides, cytokines, and other inflammatory mediators in the etiology and frequency of heat injury in Marine recruits. • 750 Incorporate models of peripheral and central cardiovascular function into MERCURY to predict performance during military operations. • 1250 Transition to special operational rations dietary supplements (e.g., ginkgosides, tryptophan, tocopherols) that may improve mental performance during intensive training or operational scenarios. • 650 Conduct validation studies of countermeasures to night work and rapid deployment across multiple time zones. • 650 Evaluate the flight performance of aviators during 96 hour sleep deprivation to find best recommendation to preserve aviator operational efficacy and performance during sustained operations. • 700 Investigate the aviation performance requirements against image quality of emerging display techniques. • 700 Determine behavioral and pharmacological interventions effective in promoting recovery from deployment and battle stress. • 600 Determine impact of family well-being on soldier effectiveness and resilience. • 900 Develop and model antidote for sleep inertia. • 500 Determine feasibility of using electrical fields to accelerate stress fracture healing and rehabilitation. • 88 Develop a physiological strain index to compare and quantify heat strain in soldiers. <p>Total 8456</p>		
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BUDGET ACTIVITY 2 - Applied Research	PE NUMBER AND TITLE 0602787A Medical Technology	PROJECT A919
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COST (<i>In Thousands</i>)	FY1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY2004 Estimate	FY2005 Estimate	Cost to Complete	Total Cost
A919 Orthopedic Implant Research	2343	0	0	0	0	0	0	0	0	2343

Mission Description and Justification: By Congressional direction, this project was funded to develop a prototype artificial hip stem using the volumetrically controlled manufacturing (VCM) technique for precision fabrication using synthetic biomaterials. This will eliminate a major cause of artificial hip replacement failures.

FY 1998 Accomplishments:

- 2343 Solicited and evaluated proposals and awarded contract to develop prototype artificial hip stem using VCM technique.
- Total 2343

FY 1999 Planned Program: Project not funded in FY 1999.

FY 2000 Planned Program: Project not funded in FY 2000.

FY 2001 Planned Program: Project not funded in FY 2001.

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BUDGET ACTIVITY 2 - Applied Research	PE NUMBER AND TITLE 0602787A Medical Technology	PROJECT A920
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COST (In Thousands)	FY1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY2004 Estimate	FY2005 Estimate	Cost to Complete	Total Cost
A920 Prostate Cancer Research	37472	0	0	0	0	0	0	0	0	37472

Mission Description and Justification: By Congressional direction, the purpose of this project is to develop initial research models for prostate cancer research to include studying prostate cancer diagnosis and treatment in cooperation with the Center for Prostate Disease Research.

FY 1998 Accomplishments:

- 37472 FY 1997 and FY 1998 program funds were combined. Published a Broad Agency Announcement (BAA) in July 1997. Conducted scientific and programmatic reviews by March 1998 and made initial awards in April 1998, completed 30 September 1998. Published a supplemental Program Announcement in May 1998. Conducted programmatic review in August 1998 and made initial awards in late August 1998, to be completed by 30 September 1999.

Total 37472

FY 1999 Planned Program: Project not funded under this PE in FY 1999.

FY 2000 Planned Program: Project not funded in FY 2000.

FY 2001 Planned Program: Project not funded in FY 2001.

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BUDGET ACTIVITY 2 - Applied Research	PE NUMBER AND TITLE 0602787A Medical Technology	PROJECT A921
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COST (In Thousands)	FY1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY2004 Estimate	FY2005 Estimate	Cost to Complete	Total Cost
A921 Ovarian Cancer Research	9369	0	0	0	0	0	0	0	0	9369

Mission Description and Justification: By Congressional direction, the purpose of this project is to develop initial research models for a comprehensive preventive program in ovarian cancer that expands into endometrial, cervical, and other cancer research that would include prevention, planning, implementation, and development planning.

FY 1998 Accomplishments:

- 9369 Published a Program Announcement in June 1998. Conduct scientific peer review and programmatic review by April 1999. Initial awards will be made in May 1999 and awards completed by 30 September 1999.

Total 9369

FY 1999 Planned Program: Project not funded under this PE in FY 1999.

FY 2000 Planned Program: Project not funded in FY 2000.

FY 2001 Planned Program: Project not funded in FY 2001.

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ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)								DATE September 1998		
BUDGET ACTIVITY 2 - Applied Research				PE NUMBER AND TITLE 0602787A Medical Technology				PROJECT A927		
<i>COST (In Thousands)</i>	FY1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY2004 Estimate	FY2005 Estimate	Cost to Complete	Total Cost
A927 Biocide Materials Research	5338	0	0	0	0	0	0	0	0	5338
<p><u>Mission Description and Justification:</u> By Congressional direction, the purpose of this project is to investigate projected medical applications of Biocide technology.</p> <p>FY 1998 Accomplishments:</p> <ul style="list-style-type: none"> • 5338 Proposal processed and funding received by primary contractor, Defense Supply Center, Columbus (DSSC). Battelle is a subcontractor to DSCC on this effort. <p>Total 5338</p> <p>FY 1999 Planned Program: Project not funded in FY 1999.</p> <p>FY 2000 Planned Program: Project not funded in FY 2000.</p> <p>FY 2001 Planned Program: Project not funded in FY 2001.</p>										
Project A927			<i>Page 37 of 43 Pages</i>				Exhibit R-2A (PE 0602787A)			

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ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)								DATE September 1998		
BUDGET ACTIVITY 2 - Applied Research				PE NUMBER AND TITLE 0602787A Medical Technology				PROJECT A948		
<i>COST (In Thousands)</i>	FY1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY2004 Estimate	FY2005 Estimate	Cost to Complete	Total Cost
A948 Portable Cardiopulmonary Bypass Pump and Oxygenator	0	1986	0	0	0	0	0	0	0	1986
<p><u>Mission Description and Justification:</u> By Congressional direction, conduct research to advance cardiopulmonary bypass pump and oxygenator technology.</p> <p>FY 1998 Accomplishments: Project not funded in FY 1998.</p> <p>FY 1999 Planned Program:</p> <ul style="list-style-type: none"> • 1933 Execute program plan based upon Congressional guidance. • 53 Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs. <p>Total 1986</p> <p>FY 2000 Planned Program: Project not funded in FY 2000.</p> <p>FY 2001 Planned Program: Project not funded in FY 2001.</p>										
Project A948			<i>Page 38 of 43 Pages</i>				Exhibit R-2A (PE 0602787A)			

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BUDGET ACTIVITY 2 - Applied Research	PE NUMBER AND TITLE 0602787A Medical Technology	PROJECT A949
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COST (In Thousands)	FY1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY2004 Estimate	FY2005 Estimate	Cost to Complete	Total Cost
A949 Advanced Cancer Detection	0	3478	0	0	0	0	0	0	0	3478

Mission Description and Justification: By Congressional direction, the purpose of this appropriation is to continue support for the ongoing Advanced Cancer Detection Center.

FY 1998 Accomplishments: Project not funded under this PE in FY 1998.

FY 1999 Planned Program:

- 3386 Evaluate, oversee, and monitor the research findings and future proposals. Continue support to ongoing research at the University of South Florida Advanced Cancer Detection Center.
- 92 Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs

Total 3478

FY 2000 Planned Program: Project not funded in FY 2000.

FY 2001 Planned Program: Project not funded in FY 2001.

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ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)								DATE September 1998		
BUDGET ACTIVITY 2 - Applied Research				PE NUMBER AND TITLE 0602787A Medical Technology				PROJECT A950		
<i>COST (In Thousands)</i>	FY1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY2004 Estimate	FY2005 Estimate	Cost to Complete	Total Cost
A950 Teleradiology	0	2980	0	0	0	0	0	0	0	2980
<p><u>Mission Description and Justification:</u> By Congressional direction, this program funds continuation of efforts to develop experimental technologies that will allow medical imaging to be deployed in remote and far-forward locations. Additionally, this program will fund the research for the development of imaging networks that can deliver medical studies for interpretation.</p> <p>FY 1998 Accomplishments: Project not funded in FY 1998.</p> <p>FY 1999 Planned Program:</p> <ul style="list-style-type: none"> • 2902 Grant awarded for cooperative research effort between the Uniformed Services University of the Health Sciences (USUHS) and the University of South Florida (USF). • 78 Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs <p>Total 2980</p> <p>FY 2000 Planned Program: Project not funded in FY 2000.</p> <p>FY 2001 Planned Program: Project not funded in FY 2001.</p>										
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BUDGET ACTIVITY 2 - Applied Research	PE NUMBER AND TITLE 0602787A Medical Technology	PROJECT A951
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COST (<i>In Thousands</i>)	FY1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY2004 Estimate	FY2005 Estimate	Cost to Complete	Total Cost
A951 Diagnostic and Surgical Breast Imaging	0	1987	0	0	0	0	0	0	0	1987

Mission Description and Justification: By Congressional direction, the purpose of this program is to conduct research in Diagnostic and Surgical Breast Imaging.

FY 1998 Accomplishments: Project not funded in FY 1998.

FY 1999 Planned Program:

- 1934 Publish a Program Announcement in March 1999. In FY 2000, using FY 1999 funds, conduct scientific peer review and programmatic review by November 1999. Make initial awards in December 1999 with all awards completed no later than 30 September 2000.
- 53 Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs

Total 1987

FY 2000 Planned Program: Project not funded in FY 2000.

FY 2001 Planned Program: Project not funded in FY 2001.

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ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)	DATE September 1998
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BUDGET ACTIVITY 2 - Applied Research	PE NUMBER AND TITLE 0602787A Medical Technology	PROJECT A952
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COST (<i>In Thousands</i>)	FY1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY2004 Estimate	FY2005 Estimate	Cost to Complete	Total Cost
A952 Musculoskeletal Injuries	0	1987	0	0	0	0	0	0	0	1987

Mission Description and Justification: By Congressional direction, the purpose of this project is to develop initial research models for musculoskeletal injuries.

FY 1998 Accomplishments: Project not funded in FY 1998.

FY 1999 Planned Program:

- 1934 Evaluate competitive contracts/grants to initiate research on musculoskeletal injuries.
 - 53 Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs
- Total 1987

FY 2000 Planned Program: Project not funded in FY 2000.

FY 2001 Planned Program: Project not funded in FY 2001.

UNCLASSIFIED

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)								DATE September 1998		
BUDGET ACTIVITY 2 - Applied Research				PE NUMBER AND TITLE 0602787A Medical Technology					PROJECT A953	
<i>COST (In Thousands)</i>	FY1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY2004 Estimate	FY2005 Estimate	Cost to Complete	Total Cost
A953 Disaster Relief and Emergency Medical Services	0	9933	0	0	0	0	0	0	0	9933
<p>Mission Description and Justification: By Congressional direction, this program funds efforts to improve the delivery of emergency medical services through basic physiologic research and advances in the application of information and advanced medical technologies.</p> <p>FY 1998 Accomplishments: Project not funded in FY 1998.</p> <p>FY 1999 Planned Program:</p> <ul style="list-style-type: none"> • 9670 Continue development of disaster relief and emergency and biological medical response capability at the University of Texas – Houston. • 263 Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs <p>Total 9933</p> <p>FY 2000 Planned Program: Project not funded in FY 2000.</p> <p>FY 2001 Planned Program: Project not funded in FY 2001.</p>										
Project A953			<i>Page 43 of 43 Pages</i>				Exhibit R-2A (PE 0602787A)			

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