

Exhibit R-2, RDT&E,N Budget Item Justification

Date: February 2008

Appropriation/Budget Activity RDT&E,N BA 5			R-1 Item Nomenclature: Medical Development 0604771N				
Cost (\$ in millions)	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012	FY 2013
Total PE Cost	\$33,063	\$42,779	\$7,833	\$7,893	\$7,912	\$8,043	\$8,188
Medical/Dental Equipment Development/0933	\$7,486	\$7,803	\$7,833	\$7,893	\$7,912	\$8,043	\$8,188
Congressional Adds/9999	\$25,577	\$34,976	\$0	\$0	\$0	\$0	\$0

A. Mission Description and Budget Item Justification: The purpose of this item is to develop biomedical equipment and related techniques to reduce morbidity, to enhance the logistic feasibility of modern medical care for combat casualties, to sustain casualties for evacuation to fixed medical facilities for definitive care, and to ensure that personnel are medically qualified for military duty. Each work unit undertaken in this project has a military requirement. Efforts are justified based upon military payoff and cost benefit. There is a strong potential for dual use, technology transfer, and biotechnology firms / industry participation in the projects.

B. Program Change Summary:

	FY 2007	FY 2008	FY 2009
FY 2008 President's Budget	\$7,634	\$7,973	\$7,818
FY 2009 President's Budget	\$33,063	\$42,779	\$7,833
Total Adjustments	\$25,429	\$34,806	\$15

Program Adjustments:

Congressional Adds	\$25,577	\$35,200	\$0
Small Business Innovation Research	-\$531	\$0	\$0
Execution Realignment	\$383	-\$120	\$0
Miscellaneous Adjustments	\$0	\$0	\$15
Contract Efficiencies	\$0	-\$69	\$0
Economic Assumptions	\$0	-\$205	\$0
Total Adjustments	\$25,429	\$34,806	\$15
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C. Other Program Funding Summary:

D. Acquisition Strategy:

E. Performance Metrics:

Exhibit R-2a, RDT&E,N Project Justification						Date: DECEMBER 2007	
Appropriation/Budget Activity RDT&E,N/BA 5				Medical Development 0604771N			
Cost (\$ in millions)	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012	FY 2013
Medical/Dental Equipment Development/0933	\$7,486	\$7,803	\$7,833	\$7,893	\$7,912	\$8,043	\$8,188
RDT&E,N Articles Quantity							

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B. Accomplishments/Planned Program

	FY 2007	FY 2008	FY 2009	FY 2010
Accomplishment/Effort/Subtotal Cost	\$7,486	\$7,803	\$7,833	\$7,893
RDT&E,N Articles Quantity				

FY 2008 Plan:

Stasis Preclinical Trials for Trauma Indications - Conduct preclinical trials of an infusible hemostatic agent. The agent is designed for applications to non-compressible injuries.

Heterotopic Ossification Incidence: Identify incidence and degree of heterotopic ossification associated with trauma treatment in theater.

The Use of the Vacuum Assisted Wound Closure Device and Quantitative Bacteriology in Extremity Wound Closure - Continue data collection and analysis of VAWCD effluent for quantitative bacteriology and cytokine/growth factor expression. Complete patient enrollment and finalize data analysis.

Mobile Oxygen Ventilation and External Suction (MOVES) System - Finalize configuration for product delivery for IOC. Complete final design of MOVES anesthesia module. Initiate redesign for using MOVES in Navy Expeditionary Resuscitative Surgery System (ERRS).

Clinical Trial of a Newly Developed Forward-Deployable Dental Dressing - conduct field efficacy testing with the USMC of a novel dental treatment technology.

The Use of Anti-Oxidants to Augment Outcome in Patients with Balance Disorders After Blast Injury and Blunt Head Trauma- Initiate clinical investigations into the efficacy of antioxidants to reduce the vestibular and auditory effects of blast exposure.

Restoration of Endodontically-Treated or Compromised Teeth to Prevent or Rehabilitate Tooth Fracture Using Computer-Aided Direct Ceramic/Composite Full-Coverage Restoration - Complete efficacy studies of CEREC technology for rapid treatment of dental injuries.

Enhanced Spatial Disorientation Training: Basic, Clinical and Operational Aspects- Continue development of state of the art spatial orientation technologies to investigate methods for mitigation spatial disorientation in aviators.

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RDT&E,N Articles Quantity							

FY 2008 Plan:

Cricothyroidotomy Device - Final configuration designs of a novel cricothyroidotomy device for use in far-forward battle areas. This is a joint program with the USMC and US Army.

Refinement and Development of Medical Planning Factors Among the Services - Finalize evaluation of modelling technologies for medical planning. Update and augment algorithms using data collected from CTR and other sources. Final Report

Development of Capability-Based Expeditionary Medical Treatment Facilities - Complete data collection and analysis for updating and resupply. Integrating with TML+ continues. Publish final report.

Improved Administration of Anti-Motion Sickness Medications - Finalize data collection and report preparation. Complete development of guidelines for dissemination and final transition to USSOCOM and NOMI. Final Report.

Joint Development Projects with MARCORSYSCOM Medical Acquisition - Initiate Joint Development Testing and Evaluation program for medical products and equipment. Finalize development for USMC Procurement.

Transition Projects from Force Health Protection Future Capability - Initiate Development, Testing, and Evaluation program for transition products from the Office of Naval Research 6.3 Advanced Development program. Focus will be on transition of novel hemostatic agents (e.g. infusible hemostatics and field/first responder devices).

RHESUS: Restore Effective Survival in Shock - Initiate Phase I/II clinical trials for use of Hemoglobin-based Oxygen Carrier in trauma treatment.

Establishing a 3D Craniofacial Image Protocol and Pre-Injury Database - Establish a pre-traumatic 3D image database for soft and hard tissue for use to re-establish structures for reconstruction of craniofacial abnormalities. Fabricate surgical guides to decrease OR time and increase predictability of surgical outcomes.

Validation of a Readiness to Fly Assessment Tool - Develop an operational readiness assessment tool that is web- or computer-based to assess an aviator's readiness to fly based on cognitive abilities crucial to heavy mental workload of aircraft operations and the effects of fatigue.

Development of the Medical Force Planning Factors - Measure the effectiveness of combat casualty medical care and preventive gear.

LED Surgical Lamp for FRSS - Complete development of a light-weight, 21-LED surgical lamp that will operate under extreme conditions.

Disposable Chair-Side Amalgam Separation System for Dental Chairs - Finalize an amalgam separation system to remove mercury and other heavy metals from wastewater leaving Navy dental treatment facilities.

Clinical Evaluation of a Vaxfectin TM - Formulated Tetravalent Dengue DNA Vaccine (VTDDV) - Initial clinical investigations trials on four serotypes of dengue.

Evaluation of HemCon's Dental Dressing for Controlling Hemorrhage - Finalize the assessment of the stability/shelf-life of the product under extreme environmental operating conditions.

Thermal Insulation Performance of MK11 SEIE Submarine Escape Suit - Improved life draft design; compare user-reported levels of fatigue/physical discomfort associated with long durations in the MK10 raft versus the MK11 raft.

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RDT&E,N Articles Quantity							
FY 2009 Plan:							
<p><u>Joint Development Projects with MARCORSSYSCOM Medical Acquisition</u> - Initiate Joint Development Testing and Evaluation program for medical products and equipment. Finalize development for USMC Procurement.</p> <p><u>Transition Projects from Force Health Protection Future Capability</u> - Initiate Development, Testing, and Evaluation program for transition products from the Office of Naval Research 6.3 Advanced Development program. Focus will be on transition of novel hemostatic agents (e.g. infusible hemostatics and field/first responder devices).</p>							
C. Other Program Funding Summary: Not applicable							
D. Acquisition Strategy: Not applicable							
E. Performance Metrics: Not Applicable							

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RDT&E,N BA 5				
Cost (\$ in millions)	FY 2007	FY 2008	FY 2009	
9999 Congressional Adds - VARIOUS	\$25,577	\$35,200	\$0	
RDT&E,N Articles Quantity:				
A. Mission Description and Budget Item Justification: Congressional Adds.				
B. Accomplishments/Planned Program				
	FY 2007	FY 2008	FY 2009	
Accomplishment/Effort/Subtotal Cost				
RDT&E,N Articles Quantity				
Military Dental Research/2896	\$3,892	\$1,600		
Biomedical Research Imaging Core - COH National Medical Center/9003	\$1,311	\$0		
Community Hospital Telehealth Consortium/9005	\$972	\$0		
Discovery, Early Detection, Evaluation, Treatment and Prevention/9397	\$3,892	\$0		
Infusible Hemostatic Therapeutic Trials/9592	\$1,942	\$0		
Diabetes Research, Somatic Cell Processing Program/9596	\$1,363	\$1,600		
HUVACTC Proton Beam Therapy Research/9738	\$972	\$0		
On Demand Custom Body Implants/Prosthesis for Injured Personnel/9742	\$1,312	\$1,600		
Thermotube Battlefield Body Temperature/9A55	\$496	\$0		
Next Generation Networking Electronic Medical Records Project	\$6,783	\$0		
Validation of Prognostic Health Management	\$1,000			

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RDT&E,N Articles Quantity:				
A. Mission Description and Budget Item Justification: Congressional Adds.				
B. Accomplishments/Planned Program				
Center for Deployment Psychology	\$0	\$1,000		
Granular Chitosan Clotting Agent for Anti-Coagulated Hypothermic Blood	\$0	\$1,200		
Implantable Middle Ear Hearing System	\$0	\$1,000		
Mobile Oxygen, Ventilation and External Suction (MOVES)	\$0	\$2,000		
Penn State Cancer Institute	\$0	\$5,600		
Strategies to Mitigate Individual Stress Reactivity and operational Stress Reactions in the Military	\$0	\$1,200		
US Navy Pandemic Influenza Vaccine Program	\$0	\$1,600		
VisualDX Image-Based Real-Time Clinical Decision Support	\$0	\$2,400		
Multivalent Dengue Vaccine Program	\$0	\$3,000		
Next Generation Networking Electronic Medical Records Project	\$0	\$4,000		
Advanced Research and Development of Hemostatic Agents (USMC)	\$0	\$3,200		
Phase 1 Clinical Trial	\$0	\$3,200		
Hampton University Cancer Treatment Initiatives	\$0	\$1,000		

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RDT&E,N Articles Quantity:			
A. Mission Description and Budget Item Justification: Congressional Adds.			
B. Accomplishments/Planned Program FY 2008 Plans:			
Military Dental Research/2896	Develop innovative designs for dental care and dental health for CONUS and OCONUS operations. Conduct critical research in development of rapid-read diagnostic tests and other protective measures that helped reduce the severity and number of casualties due to dental and other medical emergencies.		
Infusible Hemostatic Therapeutic Trials/9592	Continue to explore the use of infusible agents in the control of non-compressible bleeding.		
Diabetes Research, Somatic Cell Processing Program/9596	Continue research to develop and demonstrate improvements in specific areas to include cell sorting, analysis, and imaging which have provided notable improvements to the cell isolation process and increase the areas of research for tissue-engineered end products.		
On Demand Custom Body Implants/Prosthesis for Injured Personnel/9742	Continue testing and evaluation of Phase I efforts to develop manufacturing methods and materials necessary for rapid prototyping and delivery of prostheses. Apply state-of-the-art CAD/CAM procedures to prosthesis manufacturing technology.		
Center for Deployment Psychology	Initiate baseline psychological reviews of the warfighter prior to deployment; psychologically prepare everyone in the realities of war; and to provide cultural awareness.		
Granular Chitosan Clotting Agent for Anti-Coagulated Hypothermic Blood	Research and establish further development of the effects of the CELOX hemostatic agents based on the positively-charged CELOX granules which bind to negatively-charged red blood cells, thus forming a clotting mechanism that works independently of biological blood-clotting factors, requiring further research of how CELOX can be used on heparinized blood.		
Implantable Middle Ear Hearing System	Continue to investigate the military applicability of implantable hearing systems that counter the effects of noise-induced hearing loss without the drawbacks of conventional hearing aids.		
Mobile Oxygen, Ventilation and External Suction (MOVES)	Continue prototyping of the Monitoring, Oxygen Ventilation and External Suction System (MOVES) beta model to allow for the completion of the animal, human factors, and human clinical testing of MOVES. Beta development is planned for FY08 as a next generation research and development spiral, based on feedback from the warfighter, which will then address FDA approval once all testing has been completed.		
Penn State Cancer Institute	Continuation of R&D efforts in support of the new Penn State Cancer Institute (PSCI) and the focus on expansion of translational cancer research capabilities in the areas of the breast, colon, and treatment of cancer.		

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RDT&E,N Articles Quantity:			
A. Mission Description and Budget Item Justification: Congressional Adds.			
B. Accomplishments/Planned Program			
Strategies to Mitigate Individual Stress Reactivity and operational Stress Reactions in the Military	Develop stress-coping resources and interventions for combat deployed military personnel, their families, and the providers who support their psychological health needs. Educational materials and self-help exercises will be developed to assist returning war veterans as they readjust to domestic conditions and reintegrate with their families. Training materials will be developed for both active duty and civilian providers, to enhance their ability to recognize the signs and symptoms of combat stress and provide optimal treatment.		
US Navy Pandemic Influenza Vaccine Program	Conduct research to understand mechanistically how immune responses in the respiratory tract are initiated and regulated. The information will facilitate the improvement of existing vaccines and promote the development of new vaccine strategies meant to elicit long-lasting protective immunity against respiratory pathogens.		
VisualDX Image-Based Real-Time Clinical Decision Support	Continue to validate the usefulness and technical feasibility of the VisualDx software within the theater of combat healthcare system and to evaluate the benefits of VisualDx in terms of force health protection and readiness.		
Multivalent Dengue Vaccine Program	Continue work to manufacture the two vaccine mixture under GMP conditions for a Phase I clinical investigation; execution of the Phase I clinical trial; and develop and test a single vaccine candidate that will produce neutralizing antibodies against all four serotypes in vaccinated animals.		
Next Generation Networking Electronic Medical Records Project	Continue to evaluate and demonstrate the networking, distribution and data sharing efficiencies that can be achieved through the use of technologies such as dynamic layer 7 routing. The phase-III portion of the project will further demonstrate the capability of a highly advanced integrated service platform to solve problems of network performance latency, scalability and integration complexity. Objective is to design and deploy solutions that demonstrates the ability to (a) solve the above listed issues common to all networked services, (b) highlight these benefits for Electronic Medical Record (EMR) services such as Medweb, BMIST, AHLTA, and (c) allow high-level and exponential extensibility to other networked services either intra-agency, inter-service; and across secure and non-secure networks while maintaining the integrity of security and location across networks		
Advanced Research and Development of Hemostatic Agents (USMC)	Research improved functional modification to the QuikClot® hemostat in an effort to establish advanced functional applications and benefits of this sterile, traumatic wound treatment that rapidly arrests high-volume blood loss and achieves hemostasis in large wounds, arresting the hemorrhage before the casualty goes into shock.		
Hampton University Cancer Treatment Initiatives	Initiation of R&D efforts in support of diagnosis and treatment of cancer.		
C. Other Program Funding Summary: Not applicable			
D. Acquisition Strategy: Not Applicable			
E. Performance Metrics: Not Applicable			