Exhibit R-2, RDT&E,N Budget Item Justification							Date: May 2009	
Appropriation/Budget Activity RDT&E,N BA 5				R-1 Item Nomenclature: Medical Development 0604771N				
Cost ($ in millions)	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015
Total PE Cost	49.656	39.725	9.888	0.000	0.000	0.000	0.000	0.000
Medical/Dental Equipment Development/0933	16.684	7.812	9.888	0.000	0.000	0.000	0.000	0.000
Congressional Adds/9999	32.972	31.913	0.000	0.000	0.000	0.000	0.000	0.000

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 2008	FY 2009	FY 2010	FY 2011
FY 2009 President's Budget	42.779	7.833	7.893	0.000
FY 2010 President's Budget	49.656	39.725	9.888	0.000
Total Adjustments	6.877	31.892	1.995	0.000
Program Adjustments:				
Congressional Rescissions	0.000	0.000	0.000	0.000
Congressional Adjustments	0.000	32.000	0.000	0.000
Full Supplemental	0.000	0.000	0.000	0.000
SBIR/STTR/FTT Assessment	1.344	0.000	0.000	0.000
Rate/Miscellaneous Adjustments	5.533	-0.108	2.160	2.618
Total Adjustments	6.877	31.892	2.160	2.618

C. **Other Program Funding Summary:**

D. **Acquisition Strategy:**

E. **Performance Metrics:**

Exhibit R-2a, RDT&E,N Project Justification							Date: May 2009	
Appropriation/Budget Activity RDT&E,N/BA 5				Medical Development 0604771N				
Cost ($ in millions)	FY 2008	FY 2009	FY 2010					
Medical/Dental Equipment Development/0933	16.684	7.812	10.053					
RDT&E,N Articles Quantity								

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. **Accomplishments/Planned Program**

		FY 2008	FY 2009	FY 2010	FY 2011		
Accomplishment/Effort/Subtotal Cost		16.684	7.812	9.888	0.000		
RDT&E,N Articles Quantity							

FY 2008 Accomplishments:

Stasix® Preclinical Trials for Trauma Indications - Completed preclinical trials of Stasix® infusible hemostatic agent. Identified effective dosage for delivery in animal model. Resulting hemostatis in liver injury model produced significant increase in survival over control. This effort provided baseline input for advanced preclinical trials to be initiated in FY09.

Heterotopic Ossification (HO) Incidence - Completed analysis incidence and degree of heterotopic ossification associated with trauma treatment in theater. Incidence of HO is significantly higher in combat trauma than civilian trauma. Mechanisms of HO in combination with wound healing investigated to produce interventions. Preparing recommendations on use of psychotropic drug that negatively affect HO outcomes in polytrauma patients.

The Use of the Vacuum Assisted Wound Closure Device and Quantitative Bacteriology in Extremity Wound Closure - Baysian modelling allows prediction of likelihood of effective wound closure. This outcome can reduce by 50% the facilities and procedures required for definitive closure in an MTF. This program is complete. The results are transitioning into an FY09 Comprehensive Wound Treatment Effort. Preparing submission to FDA for approval of biomarker panel for MTF implementation in comprehensive wound repair regimen.

Monitoring Oxygen Ventilation and External Suction (MOVES) System - Established test protocols for airworthiness testing. Finalized configuration for initial and Low Rate Initial Production (LRIP) product delivery. Continued design configuration of MOVES anesthesia module. Continued investigations of redesign for using MOVES in other naval platforms and in the Navy Expeditionary Resuscitative Surgery System (ERSS). This is a joint program with MARCORSYSCOM.

FY 2008 Accomplishments (Continued):

Clinical Trial of a Newly Developed Forward-Deployable Dental Dressing - Completed field trials of DentStat (syringe delivery system) with 1st Dental BN, Camp Pendleton, CA (Nov 07). Completed clinical trials of DentStat chemistry (two-bottle delivery system) (Mar 08). Final modifications made to the syringe delivery system.

The Use of Anti-Oxidants to Augment Outcome in Patients with Balance Disorders After Blast Injury and Blunt Head Trauma - Continued 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 - Proof of principle test was conducted to forward images of the crown preparation and was successfully transferred via email. Images are provided to NIDBR personnel to conduct in-laboratory re-construction and fabrication for extensive testing protocols to determine outcomes. Two CAD/CAM units have been deployed for testing.

Enhanced Spatial Disorientation Training: Basic, Clinical and Operational Aspects - Continued development of spatial orientation technologies to investigate methods for mitigation spatial disorientation in aviators. Finalizing package for implementation of findings in training scenarios.

Cricothyroidotomy Device - Received 100 prototype devices of final version 4 configuration designs. Demonstrated systems to JTF-CAPMED, USSOCOM, and Defense Medical Standardization Board representatives. Completed version 5.1 design for use in forward battle areas. Developed Phase I of Test Plan for ruggedization of packaging and prototype instruments. This is a joint program with the USMC and US Army.

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

Establishing a 3D Craniofacial Image Protocol and Pre-Injury Database - Hardware required for establishing data storage and retrieval systems has been procured. Protocols for the verification of the equipment and the accuracy of Cone beam to conventional CT are approved. Proof of concept in verification of technique has been accomplished and results have been reported via Table Clinic at National Meeting and submission for publications.

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.

FY 2008 Accomplishments (Continued):

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

Light Emitting Diode (LED) Surgical Lamp for Forward Resuscitative Surgical System (FRSS) - Completed design and initial specifications of a light-weight, 21-LED surgical lamp that will operate under extreme conditions. Completed design of battery module for field use.

Clinical Evaluation of a Vaxfectin TM - Formulated Tetravalent Dengue DNA Vaccine (VTDDV) - Preparation for clinical investigations trials on four serotypes of dengue. Contract in place for GMP tetravalent dengue DNA vaccine in proprietary adjuvant (vexfectin) 5-10g per plasmid for 4 plasmids. Preparations for progress in large scale production and development of regulatory support initiated.

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

Improved Submariner Eyewear for Routine Wear and Emergency Equipment Use Underway - Identified candidate eyewear and developed instruments for assessment of human factors during emergency scenarios. Transition activities are to be coordinated through Navy Optometry.

Thermal Insulation Performance of MK11 SEIE Submarine Escape Suit - Completed draft design/collection of user-reported levels of fatigue/physical discomfort associated with long durations in the MK10 raft versus the MK11 raft. Information product transition efforts are coordinated with SUBFORCE.

Supplemental for Wound Research - Evaluate the potential of amnion-derived progenitor cells for treating combat wounds in a standardized animal model of acute injury. Work includes supporting molecular and cellular studies related to the use of the progenitor cells. These studies include biomarker analyses that provide specific, quantifiable end-points for clinical outcomes. Related components of the project are directed toward enhanced treatment of acute and chronic wounds, wound care, and associated technologies.

FY 2009 Plan:

PreClinical Trials for FDA approval of an Infusible Hemostatic Agent - Initiate final preclinical trials of platelet derived hemostatic agents. Two candidate agents will be compared in a parallel effort. The outcomes will drive subsequent FDA Safety/Efficacy Trials of the infusible hemostatic agent selected from preclinical tests. The agent is designed for applications to non-compressible injuries.

Heterotopic Ossification Incidence - Clinical procedures for reducing the incidence and severity of Heterotopic Ossification (HO) associated with traumatic injury. Identify potential modifications of clinical causes and timing of interventions.

The Use of the Vacuum Assisted Wound Closure Device and Quantitative Bacteriology in Extremity Wound Closure transitioning to Wound Management Program - Finalize Clinical Protocols for use of cytokine/growth factor expression in reducing associated debridement and irrigation. Initiate transition to standard clinical practice at MTF.

FY 2009 Plan (Continued):

Monitoring, Oxygen Ventilation and External Suction (MOVES) System - Conduct reconfiguration of MOVES to reduce weight and cost for subsequent production runs. Incorporate joint service requirements. Continue Configuration Management of MOVES anesthesia module.

Forward-Deployable Dental Dressing Developmental/Operational Test and Evaluation - Final Field Testing of ruggedized delivery system for the novel dental dressing.

Restoration of Endodontically-Treated or Compromised Teeth to Prevent or Rehabilitate Tooth Fracture Using Computer-Aided Direct Ceramic/Composite Full-Coverage Restoration - Initiate transition of CEREC protocols to clinical practice.

Cybertech Cric Cricothyroidotomy Device - Conduct late Developmental Test & Evaluation for human factors and ruggedization of Low Rate Initial Production cricothryoidotomy devices. This is a joint program with the USMC and US Army.

Refinement and Development of Medical Planning Factors Among the Services - Finalize modelling technologies for medical planning. Update and augment algorithms using data collected from available data sources. Transition final product to medical planners.

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 Naval 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).

Establishing a 3D Craniofacial Image Protocol and Pre-Injury Database - Continue refinement of the pre-traumatic 3D image database for soft and hard tissue for use to re-establish structures for reconstruction of craniofacial abnormalities or traumatic injuries. Resulting images will be used for surgical guides to decrease OR time and increase predictability of surgical outcomes.

Validation of a Readiness to Fly Assessment Tool - Continue Validation of an operational readiness assessment tool. The tool is computer-based and used 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.

Clinical Evaluation of a Vaxfectin TM - Formulated Tetravalent Dengue DNA Vaccine (VTDDV) - Continue 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.

FY 2010 Plan:

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

Phase I Clinical Trials for FDA approval of an Infusible Hemostatic Agent - Complete Phase I Safety Trials of the infusible hemostatic agent selected from preclinical tests. The agent is designed for applications to non-compressible injuries. Transition to US Army Medical Materials Development Agency for Phase II.

Mobile Oxygen Ventilation and External Suction (MOVES) Anesthesia - Continue Development of MOVES anesthesia module.

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).

C. **Other Program Funding Summary:** Not applicable

D. **Acquisition Strategy:** Not applicable

E. **Performance Metrics:** Not Applicable

Exhibit R-2a, RDT&E,N Budget Item Justification							Date: May 2009
Appropriation/Budget Activity RDT&E,N BA 5				Medical Development 0604771N			
Cost ($ in millions)	FY 2008	FY 2009	FY 2010				
9999 Congressional Adds - VARIOUS	32.972	31.913	0.000				
RDT&E,N Articles Quantity:							
A. **Mission Description and Budget Item Justification:** Congressional Adds.							
B. **Accomplishments/Planned Program**							
	FY 2008	FY 2009					
Accomplishment/Effort/Subtotal Cost							
RDT&E,N Articles Quantity							
Military Dental Research	1.543	5.984					
Infusible Hemostatic Agent Clinical Trials - Phase 1	3.085						
Somatic Cell Processing Program (Diabetes Research)	1.543						
On Demand Custom Body Implants/Prosthesis for Injured Personnel	1.543	1.596					
Granular Chitosan Clotting Agent for Anti-Coagulated Hypothermic Blood	1.157						
Implantable Middle Ear Hearing System	0.965						
Mobile Oxygen, Ventilation and External Suction (MOVES)	1.928	1.197					
Discovery, Early Detection, Eval Treat & Prev in Cancer Research (Penn State Cancer Institute)	5.396	2.792					
Strategies to Mitigate Individual Stress Reactivity and Operational Stress Reactions in the Military	1.157						
US Navy Pandemic Influenza Vaccine Program	1.543	1.596					
VisualDX Image-Based Real-Time Clinical Decision Support	2.314						
Multivalent Dengue Vaccine Program	2.892						
Next Generation Networking Electronic Medical Records Project	3.856						

Exhibit R-2a, RDT&E,N Budget Item Justification							Date: May 2009
Appropriation/Budget Activity RDT&E,N BA 5			Medical Development 0604771N				
Congressional Continued:							
Advanced Research and Development for Hemostatic Agents (USMC)	3.085						
Hampton University Cancer Treatment Initiatives	0.965	7.977					
Advanced Molecular Medicine Initiative		1.995					
Composite Tissue Transplantation for Combat Wounded		1.995					
Disposable Biocidal Medical Masks for NAMRU Evaluation		0.798					
HEALTHeForce		2.792					
Topical Hemostat Effectiveness Study		0.798					
U.S. Navy Cancer Vaccine Program		2.393					
FY 2008 Accomplishments:							
Military Dental Research	Consultation Service. Provided evaluation results for incorporation into Authorized Dental Allowance List (ADAL) 662 - Field Dental Operatory. Completed studies of immediate antimicrobial treatment of contaminated wounds. Results indicate that salts of fluoride (Silver and Zinc) had the most potent antimicrobial effect.						
Infusible Hemostatic Therapeutic Trials	Continued to explore the use of infusible agents in the control of non-compressible bleeding. Results were important in establishing the clinical protocols to be used for Phase I clinical trials in thrombocytopenic patients.						
Diabetes Research, Somatic Cell Processing Program	Continued research to develop and demonstrate improvements in cell sorting, analysis, and imaging. The results 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	Continued 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	Reprogrammed for FY08						

FY 2008 Accomplishments (Continued):	
Implantable Middle Ear Hearing System	Continued 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. The results will be available for incorporation into the overall plan to address the major DoD effort to mitigate Noise-Induced Hearing Loss.
Mobile Oxygen, Ventilation and External Suction (MOVES)	Completed protyping of the Monitoring, Oxygen Ventilation and External Suction System (MOVES). This will allow completion of the animal, human factors, and human clinical testing of MOVES. LRIP is planned for 2Q FY09 as a next generation spiral. With production beginning in CY09.
Penn State Caner Institute	Continued R&D efforts supporting the new Penn State Cancer Institute (PSCI). Results of the efforts will direct future focus on expansion of translational cancer research capabilities in the areas of the breast, colon, and treatment of cancer.
Strategies to Mitigate Individual Stress Reactivity and operational Stress Reactions in the Military	Developed 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 developed could assist returning war veterans as they readjust to domestic conditions and reintegrate with their families. Developing Training materials for both active duty and civilian providers, to enhance their ability to recognize the signs and symptoms of combat stress and
VisualDX Image-Based Real-Time Clinical Decision Support	combat healthcare system and to evaluate the benefits of VisualDx in terms of force health protection and readiness.
Multivalent Dengue Vaccine Program	Continued 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 produces neutralizing antibodies against all four sterotypes in vaccinated animals.
Next Generation Networking Electronic Medical Records Project	achieved through the use of technologies such as dynamic layer 7 routing. The phase-III effort further demonstrates the capability of a highly advanced integrated service platform to solve problems of network performance latency, scalability and integration complexity. Demonstrated the ability to solve issues common to networked services, evolved definition of the benefits for Electronic Medical Record (EMR) services such as Medweb, BMIST, AHLTA, and high-level and exponential extensibility to other networked services.
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	Research and development efforts were continued that support advancement of technologies for diagnosis and treatment of cancer.

Exhibit R-2a, RDT&E,N Budget Item Justification		Date: May 2009
Appropriation/Budget Activity RDT&E,N BA 5	Medical Development 0604771N	
FY09 Plans:		
Military Dental Research	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	
Advanced Molecular Medicine Initiative	This initiative seeks to revolutionize cancer treatment by identifying a patient's individual cancer cells for a more effective and less toxic treatment of cancer and to understand more fully why the human immune system fails to recognize cancer cells.	
Composite Tissue Transplantation for Combat Wounded	This effort will establish a multidisciplinary center for the systematic study of composite tissue transplantation. This center would conduct mechanistic studies on the immune response and rejection of transplanted tissues and establish a capability to conduct clinical trials in hand transplantation. The program will include a strategy to collect and analyze clinical data and materials to further the knowledge base on composite tissue transplants and be used to develop novel immunosuppressive treatments.	
On Demand Custom Body Implants/Prosthesis for Injured Personnel	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.	
Disposable Biocidal Medical Masks for NAMRU Evaluation	Conduct field and laboratory evaluation of human factors and efficacy of N95 Respirator with antimicrobial protection (Triosyn). Masks will be evaluated for form, fit, and function in select environments where conventional masks are used. Focus will be on field evaluations where infection	
HEALTHeForce	Established goals for this project include continuing to deliver quality product and services to West Virginia clinics that support rural health and provide additional capabilities and features tailored to this state. Examples of these features are additional chronic disease registries guided by national standards and local clinical input, ePrescribing, and enhanced patient education and support the expansion of HEALTHeWV program in collaboration with the National Technology Transfer Center.	
Mobile Oxygen, Ventilation and External Suction (MOVES)	Initiate reconfiguration of Low Rate Initial Production (LRIP) units Monitoring, Oxygen Ventilation and External Suction System (MOVES) human factors, weight, cube and cost. Reconfiguration of MOVES is specifically targeted to reduce weight and cost. Incorporate requirements from other services into LRIP units as part of the planned next generation research and development spiral. Configuration will be based on feedback from the warfighter and joint requirements for en-route care.	
Penn State Caner 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.	

Exhibit R-2a, RDT&E,N Budget Item Justification		Date: May 2009
Appropriation/Budget Activity RDT&E,N BA 5	Medical Development 0604771N	
FY09 Plans (Continued):		
U.S. Navy Cancer Vaccine Program	This project will develop a novel prostate cancer vaccine developed by Oncbiomune, LLC and suppor the development of an IND submission needed for FDA approval. The project supports a Phase IA/B clinical trial to be carried out at the VA San Diego Healthcare System, located in San Diego, CA. US military veterans who have received previous treatment (surgery, radiation or radioactive seed implants) and now have a rising PSA will participate in the study.	
Hampton University Cancer Treatment Initiatives	R&D efforts in support of continued progress in advanced technologies for diagnosis and treatment of cancer. Particular emphasis is placed on military and military veterans.	

C. Other Program Funding Summary: Not Applicable

D. Acquisition Strategy: Not Applicable

E. Performance Metrics: Not Applicable