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Exhibit R-2, RDT&E Budget Item Justification: PB 2012 Defense Advanced Research Projects Agency **DATE:** February 2011

APPROPRIATION/BUDGET ACTIVITY				R-1 ITEM NOMENCLATURE							
0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 2: <i>Applied Research</i>				PE 0602115E: <i>BIOMEDICAL TECHNOLOGY</i>							
COST (\$ in Millions)	FY 2010	FY 2011	FY 2012 Base	FY 2012 OCO	FY 2012 Total	FY 2013	FY 2014	FY 2015	FY 2016	Cost To Complete	Total Cost
Total Program Element	-	-	110.000	-	110.000	95.400	99.400	88.000	88.000	Continuing	Continuing
BT-01: <i>BIOMEDICAL TECHNOLOGY</i>	-	-	110.000	-	110.000	95.400	99.400	88.000	88.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

This Program Element is budgeted in the applied research budget activity because it will focus on medical related technology, information, processes, materials, systems, and devices encompassing a broad spectrum of DoD challenges. Biowarfare defense includes the capability to predict and deflect pathogen evolution of natural and engineered emerging threats and therapeutics that increase survivability within days of receipt of an unknown pathogen. Continued understanding of infection biomarkers will lead to developing a detection device that can be self-administered and provide quicker ability to diagnose and prevent widespread infection in-theater. Other battlefield technologies includes a soldier-portable hemostatic wound treatment system, capability to manufacture field-relevant pharmaceuticals in theater, and a rapid after-action review of field events as a diagnostic tool for improving the delivery of medical care and medical personnel protection. Improved medical imaging will be approached through new physical properties of cellular metabolic activities. New neural interface technologies will reliably extract information from the nervous system to enable control of the best robotic prosthetic-limb technology. To allow medical practitioners the capability to visualize and comprehend the complex relationships across patient data in the electronic medical record systems, technologies will be developed to assimilate and analyze the large amount of data and provide tools to make better informed decisions for patient care. In the area of medical training, new simulation-based tools will rapidly teach increased competency in an open and scalable architecture to be used by all levels of medical personnel for basic and advanced training. This project will also pursue the applied research efforts for dialysis-like therapeutics.

B. Program Change Summary (\$ in Millions)	FY 2010	FY 2011	FY 2012 Base	FY 2012 OCO	FY 2012 Total
Previous President's Budget	-	-	-	-	-
Current President's Budget	-	-	110.000	-	110.000
Total Adjustments	-	-	110.000	-	110.000
• Congressional General Reductions		-			
• Congressional Directed Reductions		-			
• Congressional Rescissions	-	-			
• Congressional Adds		-			
• Congressional Directed Transfers		-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-	-			
• TotalOtherAdjustments	-	-	110.000	-	110.000

Change Summary Explanation

FY 2012: Increase reflects establishment of a new PE for biomedical applied research.

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C. Accomplishments/Planned Programs (\$ in Millions)		FY 2010	FY 2011	FY 2012
Title: Unconventional Therapeutics* Description: * Previously funded in PE 0602383E, Project BW-01 <p>This thrust is developing unique and unconventional approaches to ensure that soldiers are protected against a wide variety of naturally occurring, indigenous or engineered threats. This program will develop approaches to counter any natural or anthropogenic pathogen within one week. This includes development of countermeasures that do not require prior knowledge of the pathogen and are broadly applicable to multiple unrelated bacterial and/or viral infectious agents. The integration of academic research programs with pharmaceutical development efforts will result in reducing the traditional drug development cycle timeframe.</p> <p>FY 2012 Plans:</p> <ul style="list-style-type: none"> - Demonstrate various technologies that can increase the median infectious dose (ID50) of a given pathogen by 100-fold in an animal model compared to the untreated control ID50 in order to prevent infection. - Demonstrate a 4-fold increase in survival time after a lethal dose (LD95) challenge of a given pathogen in an animal model due to administered technology. - Demonstrate 95% survival against a first LD95 challenge of a given pathogen in an animal model using a therapy developed within 7 days of receipt of an unknown pathogen. - Demonstrate 95% survival after three LD95 challenges of a given pathogen in an animal model spaced 1 week apart =7 days post countermeasure. 		-	-	9.000
Title: Pathogen Defeat* Description: *Previously funded in PE 0602715E, Project MBT-02 <p>Pathogens are well known for the high rate of mutation that enables them to escape drug therapies and primary or secondary immune responses. The Pathogen Defeat thrust area will provide capabilities to predict future threats and to deflect pathogen evolution to non-human spaces such as animals, insects, and bacteria. This area will also determine malicious intent by monitoring key technology acquisitions and commercialization of potential dual-use technologies. Pathogen Defeat focuses not on the threats that are already known but rather on the threats of newly emerging agents and mutations in the future, allowing pre-emptive preparation of vaccine and therapy countermeasures.</p> <p>FY 2012 Plans:</p> <ul style="list-style-type: none"> - Demonstrate capability of evolutionary pathway of the viral system under multiple selective pressures. - Use demonstrated capability to validate the algorithms' predictions. 		-	-	19.000

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C. Accomplishments/Planned Programs (\$ in Millions)		FY 2010	FY 2011	FY 2012
<ul style="list-style-type: none"> - Use optimized winner system and algorithm to investigate virus mitigation and frequency globally to predict the timing and geographic location of reassortment events. - Model processes to accurately predict the drift and shift of virus in pre-human animal reservoirs. - Create viral reservoir specific countermeasures that reduce probability that a novel viral pathogen could transfer from animals to humans. - Establish partners for transition of immune-hardening and pathogen anti-evolution technologies. 				
Title: Autonomous Diagnostics to Enable Prevention and Therapeutics (ADEPT)* Description: *Previously funded in Synthetic Biology in PE 0601101E, Project TRS-01 The overarching goal of the Autonomous Diagnostics to Enable Prevention and Therapeutics (ADEPT) program is to increase our ability to rapidly respond to a disease or threat and improve individual readiness and total force health protection. Service members in deployed settings have limited access to health care. New methods and devices are needed to address critical conditions on-site, to allow improved care at field hospital, fleet, and air transport settings, and to enable rapid response to emerging threats. This applied research effort will focus on development of devices for integrated diagnostics across multiple echelons of care: 1) Simple to operate diagnostic devices for critical biomarkers at the point of need; 2) highly multiplexed diagnostic devices for broad spectrum diagnostic and response to emerging threats in an automated format; and, 3) the ability to rapidly develop, integrate and distribute new assays for detection of new biomarkers and emerging threats. Research thrusts include: optimization of methodologies for extraction of targeted biomarkers from a biospecimen that has been room-temperature stabilized in a dried format; demonstration of novel molecular detection approaches towards specific biomarkers; optimization of integrated simple-to-operate diagnostic devices (sample in, results out); demonstration of novel molecular approaches for multiplexed analysis over the same or different classes of biomarkers; and, integration of sample preparation and analysis methods. A companion basic research effort is budgeted in PE 0601117E, Project MED-01. FY 2012 Plans: <ul style="list-style-type: none"> - Develop new materials and methods for low power diagnostics. - Develop new reagents and reagent storage methods for deployable diagnostics. - Develop processes for clinical sample collection and preparation for deployable diagnostics. - Develop methods and optimization criteria for extraction of targeted biomarker classes for the retrospective analysis of a dried and room-temperature stable biospecimen archive card. - Develop approach for biomarker research from archived biospecimen card, as the first step towards rapid synthesis of deployable diagnostic devices against new threats. 		-	-	10.000
Title: Tactical Biomedical Technologies*		-	-	17.000

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C. Accomplishments/Planned Programs (\$ in Millions)		FY 2010	FY 2011	FY 2012
<p>Description: *Previously funded in PE 0602715E, Project MBT-02</p> <p>The Tactical Biomedical Technologies thrust will develop new approaches to deliver life-saving medical care on the battlefield. Uncontrolled blood loss is the leading cause of preventable death for soldiers on the battlefield. While immediate control of hemorrhage is the most effective strategy for treating combat casualties and saving lives, currently no method other than surgical intervention can effectively treat intracavitary bleeding. A focus in this thrust is the co-development of a materials-based agent(s) and delivery mechanism capable of damaged tissue-targeted hemostasis and wound control. This system will effectively treat compressible and non-compressible wounds regardless of geometry or location. Additionally, rapid response to emerging biological threats on the battlefield is impacted by logistical delays of delivering the necessary therapeutics. Creating a "pharmacy on demand" will enable far-forward medical providers to manufacture and produce small molecule drugs and biologics in order to ensure that the therapeutics are available when they need them.</p> <p>FY 2012 Plans:</p> <ul style="list-style-type: none"> - Demonstrate hemostatic material compatibility with Food and Drug Administration (FDA)-approved agents that control pain, infection, and inflammation. - Achieve wound treatment system unit specs including coverage of at least 0.20 square meters of tissue area, mass of less than 200 grams, and a volume less than 150 ml. - Demonstrate scale-up for large volume hemostasis agent synthesis. - Demonstrate hemostasis agent stability consistent with operational requirements. - Test and validate the wound stasis system delivery device. - Develop a plan for wound stasis system FDA approval. - Fabricate devices capable of manufacturing six field relevant pharmaceuticals. - Investigate constructing a man-portable device capable of manufacturing four field relevant pharmaceuticals. - Demonstrate limited capability of manufacturing serum, antigen, and vaccine of DoD relevance through directed activity of microbial systems. - Show efficacy and safety of manufactured end products in in-vitro models. 				
<p>Title: Military Medical Imaging*</p> <p>Description: *Previously funded in PE 0602715E, Project MBT-02</p> <p>The Military Medical Imaging thrust will develop medical imaging capabilities to support military missions and operations. The emergence of advanced medical imaging includes newly recognized physical properties of biological tissue, or metabolic pathway, or physiological function in order to map it into an image of diagnostic utility and performance. This need is ever increasing as</p>		-	-	8.000

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C. Accomplishments/Planned Programs (\$ in Millions)		FY 2010	FY 2011	FY 2012
<p>researchers and scientists seek to better understand anatomical, functional and cellular level interactions. This thrust will also address how to improve the delivery of medical care and medical personnel protection by building a simulated environment for rapid after-action review of field events generated from current military systems. The advanced development of these tools will provide a formidable arsenal of diagnostic tools for warfighter performance and care.</p> <p>FY 2012 Plans:</p> <ul style="list-style-type: none"> - Demonstrate ability to automatically detect, track, and analyze similar events and incidents in temporal and physical space. - Qualify system based on theater-relevant demonstrations and replications of scenario exercises. - Implement biologic and agent-based models to project wounds, reactions, and injury cascades following simulation of trauma. - Transition reconstructive scenario system to Service partners for pilot programs in in-theater implementation. - Obtain in vivo hydrogen and carbon-13 spectra from animal brain using quantum orbital resonance spectroscopy (QORS). - Using established animal models for traumatic brain injury (TBI) and using QORS, distinguish healthy animals from those with TBI. 				
<p>Title: Reliable Neural-Interface Technology (RE-NET)*</p> <p>Description: *Previously funded in PE 0602715E, Project MBT-02</p> <p>The Reliable Neural-Interface Technology (RE-NET) program will develop the technology needed to reliably extract information from the nervous system, and to do so at a scale and rate necessary to control many degree-of-freedom machines, such as high-performance prosthetic limbs. This program will complement ongoing neural prosthetic activities funded through other DARPA programs. These other activities study cognition and the mechanisms of higher brain function, as well as construction of upper-limb prostheses. RE-NET will develop neural interface technologies to allow the best robotic prosthetic-limb technology, recently developed by DARPA, to be reliably used throughout the life of wounded warriors that have one or more amputated limbs.</p> <p>FY 2012 Plans:</p> <ul style="list-style-type: none"> - Refine statistically validated models of neural interface reliability for both central-nervous-system (CNS) and peripheral-system interfaces. - Demonstrate reliable peripheral interface technology to increase the channel count and hence neural information content, while not compromising the already demonstrated reliability. - Develop advanced CNS interface technology to increase operational reliability and functional lifetime, while not compromising the ability to obtain large amounts of neural information. 		-	-	24.500
Title: Virtual Tricorder		-	-	9.000

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C. Accomplishments/Planned Programs (\$ in Millions)		FY 2010	FY 2011	FY 2012
<p>Description: The Virtual Tricorder program will develop technologies for analyzing and assimilating massive datasets collected on individual test subjects to visualize, understand, and assess health status by modeling and simulating biological systems. The resulting application will enable medical practitioners to visualize and understand complex relationships across patient data in electronic medical record systems. Not only will this technique allow physicians to visualize patients' health status more accurately, but it will also provide tools to predict the systemic impact (positive and negative) of pharmaceutical and other therapeutic interventions on the patient. Achieving this will require modeling the complex, multi-feature, multi-scale interactions in biological systems from the holistic perspective of systems biology rather than the traditional reductionist perspective. Virtual Tricorder will combine multiple physical/biological models to create the capability to realistically simulate numerous simultaneous physical/biological phenomena. Virtual Tricorder technology will have potential applicability in both time-critical medical settings such as a military intensive care unit (ICU) and also long-term recovery settings where patients are being treated for multiple co-morbid conditions with multiple therapeutic approaches.</p> <p>FY 2012 Plans:</p> <ul style="list-style-type: none"> - Conceptualize modeling and simulation techniques for biological systems. - Develop techniques for registration and fusion of multi-modal medical imagery (PET/MRI/CAT/sonogram). - Develop techniques for modeling physiological impact of medications and other therapeutic interventions. - Develop approaches for integrating physical and chemical measurements that range from the microscopic (pathology data) to the macroscopic (radiology data). - Initiate development of visualization techniques that scale from the tissue to the organ to the whole-body. 				
<p>Title: Training for Rapid Acquisition of Critical Knowledge (TRACK)</p> <p>Description: The Training for Rapid Acquisition of Critical Knowledge (TRACK) program will create computer simulation-based training tools to rapidly increase the level of competence of all military service members in areas where rapid training is critical. The first area that TRACK will address is military medicine. For traumatic injury, it is often the medical response that is received in the first few minutes after injury that determines survival. TRACK-Medical will create tools that can be used to train all military personnel to a level of medical competence to provide potentially life-saving treatment in the interval before a military medical professional arrives. TRACK-Medical tools will be open and scalable to be used both to teach basic lifesaving skills to all military personnel as well as deliver more advanced training for medics, corpsmen, and nurses. The tools will incorporate intelligent tutoring and will be able to test and evaluate mastery of knowledge. TRACK-Medical tools will also provide the capability to author scenarios to recreate injuries not normally seen in the civilian world and to adapt to changing wound patterns being encountered in combat.</p> <p>FY 2012 Plans:</p>		-	-	8.500

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C. Accomplishments/Planned Programs (\$ in Millions)		FY 2010	FY 2011
<ul style="list-style-type: none"> - Initiate the development of physiologically accurate medical training simulations based on user expertise and provide detailed feedback to the user based on performance. - Explore viability of deploying versions on mobile platforms for maximum distribution. 			
Title: Dialysis-Like Therapeutics Description: This thrust will develop and demonstrate dialysis-like structures that provide very high throughput (> 1.25 liters/hour) for continuous blood sensing and purification. Bench-level techniques for molecular and cellular "scrubbing" of targets such as bacteria, toxins, and select host cells from blood will be demonstrated. At the completion of the program, high throughput removal of circulating bacteria, toxins, and select host cells from blood without collateral activation of the coagulation and immunologic systems will be demonstrated. The basic research part of this program is budgeted in PE 0601117E, Project MED-01. FY 2012 Plans: <ul style="list-style-type: none"> - Develop integrated low-shear, high throughput (> 100 milliliters/hour) microfluidics components for complex fluid flow. - Demonstrate bench-level techniques for the sensing and removal of multiple blood targets including bacteria, toxins, and select host cells. 		-	-
Accomplishments/Planned Programs Subtotals		-	110.000
D. Other Program Funding Summary (\$ in Millions) N/A			
E. Acquisition Strategy N/A			
F. Performance Metrics Specific programmatic performance metrics are listed above in the program accomplishments and plans section.			