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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 0602383E: <i>BIOLOGICAL WARFARE DEFENSE</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	41.348	32.692	30.421	-	30.421	62.736	94.008	67.076	58.425	Continuing	Continuing
BW-01: <i>BIOLOGICAL WARFARE DEFENSE</i>	41.348	32.692	30.421	-	30.421	62.736	94.008	67.076	58.425	Continuing	Continuing

A. Mission Description and Budget Item Justification

DARPA's Biological Warfare Defense project is budgeted in the Applied Research Budget Activity because its focus is on the underlying technologies associated with pathogen detection, prevention, treatment and remediation. This project funds programs supporting revolutionary new approaches to biological warfare (BW) defense and is synergistic with efforts of other Government organizations.

Efforts to counter the BW threat include countermeasures to stop pathophysiologic consequences of biological or chemical attack, host immune response enhancers, medical diagnostics for the most virulent pathogens and their molecular mechanisms, collection of atmospheric trace constituents to support chemical mapping, tactical and strategic biological and chemical sensors, and integrated defensive systems. This program also includes development of a unique set of platform technologies and medical countermeasures synthesis that will dramatically decrease the timeline from military threat detection to countermeasure availability.

B. Program Change Summary (\$ in Millions)	FY 2010	FY 2011	FY 2012 Base	FY 2012 OCO	FY 2012 Total
Previous President's Budget	40.418	32.692	30.250	-	30.250
Current President's Budget	41.348	32.692	30.421	-	30.421
Total Adjustments	0.930	-	0.171	-	0.171
• Congressional General Reductions		-			
• Congressional Directed Reductions		-			
• Congressional Rescissions	-	-			
• Congressional Adds		-			
• Congressional Directed Transfers		-			
• Reprogrammings	2.002	-			
• SBIR/STTR Transfer	-1.072	-			
• TotalOtherAdjustments	-	-	0.171	-	0.171

Change Summary Explanation

FY 2010: Decrease reflects internal below threshold reprogramming and SBIR/STTR transfer.

FY 2012: Increase reflects minor repricing.

C. Accomplishments/Planned Programs (\$ in Millions)	FY 2010	FY 2011	FY 2012
Title: Unconventional Therapeutics - Medical	20.062	13.000	-

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C. Accomplishments/Planned Programs (\$ in Millions)		FY 2010	FY 2011	FY 2012
<p>Description: 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. Past successes in this effort have come from developing therapeutics that are designed to work against broad classes of pathogens. Work in this area has also uncovered new approaches to therapeutics that, rather than attacking specific pathogens, enhance innate human immune mechanisms against broad classes of pathogens. Integral to these efforts is the development of methods that rapidly identify a broad spectrum of pathogens. Not only will these approaches be more effective against known pathogens, they also promise to offer substantial protection against unknown pathogens including engineered and emerging pathogens from third-world environments.</p> <p>A current emphasis is on the discovery and development of technologies that will allow a rapid response (within weeks) to unanticipated threats, whether they are naturally encountered emerging diseases or agents from intentional attack. This thrust has a goal of radically transforming the protein design process by researching and developing new mathematical and biochemical approaches to the in silico design of proteins with specific functions. This significantly decreases the time needed and increases the probability of success for biological warfare vaccine development. An additional focus is the development of entirely new technologies that will allow the rapid, cost-effective manufacture of complex therapeutic proteins such as monoclonal antibodies and vaccine antigens; these technologies will reduce the time for biologics manufacture from years (or even decades) to only weeks. The Unconventional Therapeutics efforts will be funded in the newly created Budget Activity 2 Program Element 0602115E, beginning in FY 2012.</p> <p>FY 2010 Accomplishments:</p> <ul style="list-style-type: none"> - Tested human H1N1 subunit vaccine produced by Blue Angel/Accelerated Manufacture of Pharmaceuticals for inflammatory mediations. - Demonstrated dose efficacy for non non-egg-based vaccines using animal models and DARPA's Rapid Vaccine Assessment, an in vitro artificial immune system. - Documented vaccine contaminants, system development, and quality control to facilitate pre-investigational new drug meetings with the Food and Drug Administration (FDA). - Began developing innovative approaches to counter any known, unknown, naturally occurring or engineered pathogen. - Initiated identification of means to prevent initial infection and secondary transmission of any contagious agent from primary to secondary contact. - Began developing approaches for slowing disease progression and sustain survival from highly lethal infections until either immunity is achieved or treatment is administered. - Began developing techniques to provide temporary protection against a pathogen in which the host has no immunity against. - Began developing strategies that accelerate acquisition of effective persistent immunity before death from a lethal pathogen. <p>FY 2011 Plans:</p>				

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C. Accomplishments/Planned Programs (\$ in Millions)		FY 2010	FY 2011	FY 2012
<ul style="list-style-type: none"> - Ascertain minimal dose of vaccine necessary for antibody protection. - Further develop innovative approaches to counter any known, unknown, naturally occurring or engineered pathogen. - Demonstrate various technologies that increase the median infectious dose (ID50) of a given pathogen by 10-fold compared to the untreated control ID50 in an animal model. - Demonstrate a 2-fold increase in survival time in an animal model after a lethal dose (LD95) challenge of a given pathogen. - Demonstrate 95% survival against a first medium lethal dose (LD50) challenge of a given pathogen in an animal model using a therapy developed within 14 days of receipt of an unknown pathogen. - Demonstrate 95% survival after three LD50 challenges of a given pathogen in an animal model spaced 1 week apart = 14 days post countermeasure. 				
Title: Medical Countermeasures - Medical Description: To further develop an expedited medical countermeasure capability, emerging technologies will be integrated to address the safety considerations in the risk/benefit package required for Emergency Use Authorization (EUA) issuance to counter naturally emerging or engineered biological warfare threats. These technologies will also be focused on new safety standards to reduce the time, risk, and cost associated with licensing a new therapeutic which might be considered under an EUA. FY 2011 Plans: <ul style="list-style-type: none"> - Assess the capability for rapid manufacture of medical countermeasures based on new expression platforms such as plant and fungi. - Identify relevant genetic events resulting in changes in virus phenotypes in the presence of selective environmental pressures. FY 2012 Plans: <ul style="list-style-type: none"> - Investigate targets for high yield medical countermeasures synthesis that do not require access to the pathogen. - Review the current Emergency Use Authorization (EUA) process from end to end and identify opportunities where an integrated countermeasure pipeline could exploit technological advances created at DARPA to rapidly create a safe and potent therapy for which the Food and Drug Administration (FDA) can confidently issue an EUA. - Initiate development of predictive preclinical bioterrorism agent disease models including in silico surrogates to increase the quality and quantity of data in the risk-benefit package available for new bioterrorism countermeasures. - Begin library development for preclinical safety and efficacy biomarkers based on physiochemical and in vitro data as technologies to support new standards of safety, thereby reducing the time, risk, and cost associated with licensing a new therapeutic. - Initiate development of physiological-based pharmacokinetic/pharmacodynamic modeling and simulation for prediction of therapeutic activity in man based on preclinical library. 		-	1.000	15.919
Title: Chemical Reconnaissance*		21.286	18.692	14.502

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C. Accomplishments/Planned Programs (\$ in Millions)		FY 2010	FY 2011	FY 2012
<p>Description: *Formerly Hyperadsorptive Atmospheric Sampling Technology (HAST).</p> <p>The Chemical Reconnaissance program will enable exhaustive, accurate, and economical collection of atmospheric trace constituents to support chemical mapping of urban and military environments. The system will demonstrate materials, packaging, and extraction technologies that sample atmospheric impurities with concentrations ranging from 10 parts per trillion to 100 parts per million by volume, from 100 liter-atmospheres of gas, in less than five minutes. New systems to provide rapid, comprehensive, and quantitative trace gas analysis without preconceived lists or libraries of target chemicals will also be developed. The analysis systems will integrate sophisticated separation and spectroscopic techniques with advanced quantum chemistry algorithms to enable library-free identification and ranking (by concentration) of all components present in complex gas mixtures. This capability will revolutionize our understanding of the environment through chemical mapping and reconnaissance. Reproducible analysis of atmospheric samples using sophisticated analytical technology will yield maps of baseline conditions, natural variability, and permit detections of nefarious anomalies involving production, movement, and storage of weapons, even under shifting backgrounds driven by meteorological and seasonal events.</p> <p>FY 2010 Accomplishments:</p> <ul style="list-style-type: none"> - Tested prototype architecture using calibrated gas mixtures. - Demonstrated prototype sampling and extraction architecture using calibrated gas mixtures. - Demonstrated sampling retention and return of analytes with accuracy and fidelity. - Demonstrated ability to seal sampled trace gases before readout. - Developed advanced mass spectrometry and infrared spectroscopy instrumentation. - Demonstrated analysis of samples fidelity and accuracy in prototype analytical system. <p>FY 2011 Plans:</p> <ul style="list-style-type: none"> - Engineer portable prototype systems for autonomous collection on mobile and stationary platforms. - Integrate sample labeling with meteorological data, time, and geographic coordinates. - Extend accuracy and fidelity of sampling capsules. - Deliver and field test functional sampling technology prototypes for autonomous vehicle-borne operation. - Demonstrate adsorbent manufacturing technology and economical collection. <p>FY 2012 Plans:</p> <ul style="list-style-type: none"> - Demonstrate prototype analytical system analysis of samples with high fidelity and accuracy. - Design and validate a system to analyze a large number of samples at low cost that fits in a standard shipping container. - Integrate sampling technologies with laboratory analytical systems. 				

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C. Accomplishments/Planned Programs (\$ in Millions)		FY 2010	FY 2011	FY 2012
- Demonstrate chemical source attribution, using virtual analysis output.				
Accomplishments/Planned Programs Subtotals		41.348	32.692	30.421
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.				