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CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2 Exhibit)	DATE February 2007
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BUDGET ACTIVITY RDT&E DEFENSE-WIDE/ BA2 - Applied Research	PE NUMBER AND TITLE 0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)
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COST (In Thousands)	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012	FY 2013	Cost to Complete	Total Cost
	Actual	Estimate								
Total Program Element (PE) Cost	240904	258862	305327	216705	189404	177988	188074	188771	Continuing	Continuing
CB2 CHEMICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)	123291	128766	114744	113870	100816	91998	94854	95173	Continuing	Continuing
TB2 MEDICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)	89183	97730	151712	63773	51565	50672	52948	52995	Continuing	Continuing
TC2 MEDICAL CHEMICAL DEFENSE (APPLIED RESEARCH)	27172	30796	36881	37072	35033	33328	38282	38614	Continuing	Continuing
TR2 MEDICAL RADIOLOGICAL DEFENSE (APPLIED RESEARCH)	1258	1570	1990	1990	1990	1990	1990	1989	Continuing	Continuing

A. Mission Description and Budget Item Justification: The use of chemical and biological weapon systems in future conflicts is an increasing threat. Funding under this PE sustains a robust program, which reduces the danger of a chemical and/or biological (CB) attack and enables U.S. forces to survive and continue operations in a CB environment. The medical program focuses on development of vaccines, pretreatments, therapeutic drugs, and on casualty diagnosis, patient decontamination, and medical management. In the physical sciences area, the emphasis is on continuing improvements in CB defense materiel, including contamination avoidance, decontamination, and protection systems. This program also provides for applied research in the areas of real-time sensing and immediate biological countermeasures. This PE also provides concept and technology demonstrations of new system concepts that will shape the development for environmental monitoring, medical surveillance, and data mining/fusion/analysis subsystems. The work in this PE is consistent with the Chemical Biological Defense Program Research, Development, and Acquisition (RDA) Plan. Efforts under this PE transition to or provide risk reduction for Advanced Technology Development (PE: 0603384BP), Advanced Component Development and Prototypes (PE: 0603884BP) and System Development and Demonstration (PE: 0604384BP). This project includes non-system specific development directed toward specific military needs and therefore is correctly placed in Budget Activity 2.

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B. <u>Program Change Summary:</u>	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>
Previous President's Budget (FY 2007 PB)	246953	280422	214036	191991
FY08 President's Budget	240904	258862	305327	216705
Total Adjustments	-6049	-21560	91291	24714
a. Congressional General Reductions	0	-56010	0	0
b. Congressional Increases	0	34450	0	0
c. Reprogrammings	1428	0	0	0
d. SBIR/STTR Transfer	-2403	0	0	0
e. Other Adjustments	-5074	0	91291	24714

Change Summary Explanation:

Funding: FY08 - Realignment in support of the Transformational Medical Technology Initiative which focuses on broad-spectrum defenses against intracellular bacterial pathogens and hemorrhagic fevers (+\$69,096K TB2).
Other fund adjustments and realignments (+\$19,070K CB2; +\$6,142K TB2; -\$2,046K TC2; -\$971K TR2).

FY09 - Fund adjustments and realignments (+\$22,684K CB2; +\$8,936K TB2; -\$4,346K TC2; -\$2,560K TR2).

Schedule: N/A

Technical: N/A

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COST (In Thousands)	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012	FY 2013	Cost to	Total Cost
	Actual	Estimate	Complete							
CB2 CHEMICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)	123291	128766	114744	113870	100816	91998	94854	95173	Continuing	Continuing

A. Mission Description and Budget Item Justification:

Project CB2 CHEMICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH): This project addresses the urgent need to provide all services with defensive materiel to protect individuals and groups from Chemical and Biological (CB) threat agents in the areas of detection, identification and warning, contamination avoidance via reconnaissance, individual and collective protection, and decontamination. The project provides for special investigations into CB defense technology to include CB threat agents, operational sciences, modeling, CB simulants, and CB survivability. Of special interest are two Defense Technology Objectives (DTOs) described as follows: (1) The fate of Chemical Warfare (CW) agents following deposition onto natural and man-made materials found in operational environments including battlefields and air bases and (2) toxicological effects resulting from low-level exposure to CW agents as well as the relationships between concentration and total exposure as measured by the product of concentration and time. This project focuses on horizontal integration of CB defensive technologies across the Joint Services. The DTOs provide a means to shape the development of selected technologies within this project. Beginning in 2007, the group heading for Modeling and Simulation/Battle space Management was changed to Information Systems Technologies to be compatible with Joint Program Executive Office for Chemical and Biological Defense (JPEO-CBD) Joint Program Manager - Information Systems.

B. Accomplishments/Planned Program

	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>
Congressional Interest Items	28221	25803	0	0

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Accomplishments/Planned Program	FY2006	FY2007	FY2008	FY2009
FY 06 - Omni Spray Development of Desorption Electro-Spray Ionization (DESI). Developed DESI mass spectrometry as a means to analyze samples, in many cases without the need for sample preparation, for the rapid detection and identification of chemical warfare agents.	991	0	0	0
FY 06 - Warfare Agents Program (Defense Research Program) - Established a state-of-the-art mass spectrometer to be used for revolutionary studies on the detection and identification of potentially harmful bio-warfare and chemical agents facility for the rapid detection and identification of biological and chemical warfare agents and to develop procedures to combat their actions.	991	0	0	0
FY 06 - System for Bacterial Warfare Agent Detection - Conducted collaborative research and development to detect and identify microorganisms of military significance. Optimized a standardized process for real-time detection and identification of Bacterial Warfare Agents (BWA).	446	0	0	0
FY 06 - Nanotechnology for Detection of BW Agents - Evaluated selected representative sampling and analysis methods that are currently available, tested modifications to existing protocols, and determined optimal surface sampling and analysis strategies to maximize the detection of the target microbial agents in environmental samples.	1585	0	0	0
FY 06 - Chem-Bio Disinfection/Neutralization Effort - Provided rapid disinfection-neutralization of the threat posed by biological agents under varied scenarios including large buildings and transport facilities in an urban environment and the battlefield.	1050	0	0	0
FY 06 - Real-Time Non-Specific Viral Agent Detector - Developed and published protocols for non-enveloped viruses from naturally occurring sources using VDSC-1 virus detection technology.	991	0	0	0
FY 06 - Research on Molecular Approach to Hazardous Materials Decontamination - Continued research into the use of multi-phase systems for decontamination. Evaluated the combinations of agent/surfactant/water and agent/solid/surfactant/water.	991	0	0	0
FY 06 - Quantum Fingerprint Technology for Chem-Bio Sensing - Assessed the feasibility of using this technology for real-time monitoring of chemical agent vapors and biological agent aerosols.	1055	0	0	0
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Accomplishments/Planned Program (Cont):				
	FY2006	FY2007	FY2008	FY2009
FY 06 - Self Decontaminating Polymer System for Chemical and Biological Warfare Agents - Developed self-decontaminating, smart polymer coating systems for textiles and other structural materials capable of destroying chemical and biological warfare agents (CWAs/BWAs) on contact.	2864	0	0	0
FY 06 - Ion Mass Spectrometry (IMS) Sample Concentration and Bioagent Detection - Designed, constructed, and demonstrated a prototype water bioagent detector based on the new technologies identified and evaluated during the initial FY05 period of performance.	991	0	0	0
FY 06 - Vulnerability Determination for Air Vehicle Contamination - Assessed technology to detect hazardous chemical agents, including volatile odor signature agents, their Biochemical Sensors for the detection of chemical/biological (C/B) contamination during Aircraft Operations thru Advanced Bioreporter Technology.	991	0	0	0
FY 06 - Portable CB Detection Sensor System - Developed novel CB sensors for early warning monitoring and integration onto unmanned robotic platforms and navigation and guidance algorithms for mine clearing/IEDs/bio-hazards in GPS-denied areas. Designed and manufactured an interface for chemical and biological sensor payload for omni-directional vehicles. Developed omni-directional motion planning algorithms for sample acquisition scenarios. Developed and implemented Joint Architecture for Unmanned Systems (JAUS) protocols for universal chemical and biological sensor payload interfaces.	1387	0	0	0
Zumwalt Program for Countermeasures to Biological and Chemical Threats - FY 06 - Developed new models and sensor systems for the detection and identification of chemical and biological hazardous materials. FY 07 - Improve model development and sensor systems for the detection and identification of chemical and biological hazardous materials.	1387	1288	0	0
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Accomplishments/Planned Program (Cont):	FY2006	FY2007	FY2008	FY2009
<p>Low-Cost Protective Chem-Bio Shelters - FY 06 - Conducted an extensive survey of candidate technologies for shelter applications that are low cost, and that provide the opportunity for reducing the size, weight, and power requirements of shelter systems. Down-selected candidates to the most promising technologies and initiated evaluation of those technologies for target applications.</p> <p>FY 07 - Refine evaluation of down-selected technologies for target applications.</p>	3470	2575	0	0
<p>Theater Level Modeling of Chemical and Biological Operational Effects at the Level of Individual Soldier - FY 06 - Developed algorithms and code-based tools to leverage the benefits of CBROE modeling methods into theater-level warfare models.</p> <p>FY 07 - Refine development algorithms and code-based tools to leverage the benefits of CBROE modeling methods into theater-level warfare models.</p>	496	991	0	0
<p>Chemical Biological Defense Program Initiative Fund - FY 06 - Solicited and awarded contracts for proposals from degree-granting universities, nonprofit organizations, or commercial concerns to include small businesses, in support of the Chemical and Biological Defense Program (CBDP) to fund chemical and biological defense science and technology projects across a wide-range of military operations.</p> <p>FY 07 - Refine proposals from degree-granting universities, nonprofit organizations, or commercial concerns to include small businesses, in support of the CBDP to fund chemical and biological defense science and technology projects across a wide-range of military operations.</p>	6950	9902	0	0
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Accomplishments/Planned Program (Cont):	FY2006	FY2007	FY2008	FY2009
Nanowire Mesh Fabrics for Chem/Bio Defense - FY 06 - Fabricated barrier materials employing wire mesh technology and assessed their efficacy against chemical warfare agent simulants. Down-selected best candidate material configurations and optimize to improve protective barrier characteristics. Conducted assessment of optimized materials against simulants and chemical warfare agents. FY 07 - Refine assessment of optimized materials against simulants and chemical warfare agents.	1585	991	0	0
FY 07 - Escape Hood.	0	1783	0	0
FY 07 - Fault Protected Drives for Laser Diodes for Defense Use.	0	991	0	0
FY 07 - Specific Gas Detector.	0	991	0	0
FY 07 - Personal Protection Against Infectious Agents.	0	1783	0	0
FY 07 - Chemical Warfare Agent Fate Model Verification and Validation Phase 2.	0	991	0	0
FY 07 - Chemical/Biological Infrared Detection System.	0	1090	0	0
FY 07 - ND Center for Environmental Networked Embedded Sensor Technology (CENEST).	0	2427	0	0
Total	28221	25803	0	0

	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>
Information Systems Technology	28608	25648	25545	26863

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Accomplishments/Planned Program	FY2006	FY2007	FY2008	FY2009
<p>Information Systems Technology, CBDP Decision Capability -</p> <p>FY 06 - Continued building the analytical framework. Initiated development of a representative sensor prototype model. Continued to identify gaps in capability to conduct rapid program analysis and feasibility assessments for tool(s) development. Initiated development of selected model and database linkages between analytic framework and decision support personnel. Demonstrated the architecture of the multivariate decision support tool and developed a prototype. Developed High Level Architecture (HLA) federates and components for the CB urban experimental and evaluation simulation.</p> <p>FY 07 - Continue building the analytical framework. Continue to identify gaps in capability to conduct rapid program analysis and conduct feasibility assessments for tool(s) development. Continue development of representative prototype models for each of the capability areas. Identify critical enhancements based upon the early prototype of the multivariate decision support tool. Develop the Joint Semi-Automated Forces (JSAF) plug-ins and Urban Resolve capability for the urban experimental and evaluation simulation. Transition capability to Joint Effect Model (JEM).</p>	4192	2686	10421	12919

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Bullet Text (cont)	FY2006	FY2007	FY2008	FY2009
<p>FY 08 - Complete user-driven requirements analysis and develop prototype CBRN Investment Planning and Analysis Tool. Initiate medical modeling area of research. Verify Nuclear Biological Chemical Casualty and Resource Estimation Support Tool (NBC CREST) 5.0, a set of human response models for CBRN agent exposure, based on NATO's Allied Medical Publication 8 (AMedP-8), for utilization by Joint Program Manager, Information Systems (JPM-IS). Select and implement a respiratory tract model and develop a prototype particle size distribution (PSD) health effects model. Investigate a modeling and simulation capability that can be used to design new synergistic combinations of anti-bacterial medications for use against drug-resistant strains. Develop secondary infection models for disease spread based on small-world networks and an extension of the Susceptible Exposed Infectious Removed (SEIR) epidemiological model to account for heterogeneous mixing among sub-populations in order to provide a well-founded model for casualty estimates in JEM involving infectious/contagious diseases, both bioagent-induced and naturally occurring (Predicting Effects Due to Infectious/Contagious Diseases for JEM). Continue building the analytical framework and identify gaps in capability to conduct rapid program analysis and conduct feasibility assessments for tool(s) development. Initiate development of representative prototype models for each of the capability areas. Identify critical enhancements based upon the early prototype of the multivariate decision support tool. Continue development of the JSAF plug-ins and Urban Resolve capability for the urban experimental and evaluation simulation. Transition capability to JEM.</p>	4192	2686	10421	12919

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Bullet Text (cont)	FY2006	FY2007	FY2008	FY2009
<p>FY 09 - Continue research of modeling in the medical area. Complete the implementation of the respiratory tract model and development of the prototype particle size distribution (PSD) health effects model. Continue to investigate a modeling and simulation capability that can be used to design new synergistic combinations of anti-bacterial medications for use against drug-resistant strains. Continue to develop secondary infection models for disease spread based on small-world networks and an extension of the Susceptible-Exposed-Infectious-Removed (SEIR) epidemiological model to account for heterogeneous mixing among sub-populations in order to provide a well-founded model for casualty estimates in JEM involving infectious/contagious diseases, both bioagent-induced and naturally occurring (Predicting Effects Due to Infectious/Contagious Diseases for JEM). Continue building the analytical framework and identifying gaps in capability to conduct rapid program analysis and conduct feasibility assessments for tool(s) development. Continue development of representative prototype models for each of the capability areas. Identify critical enhancements based upon the early prototype of the multivariate decision support tool. Complete development of the JSAF plug-ins and Urban Resolve capability for the urban experimental and evaluation simulation and transition capability to JEM. Initiate filling critical data gaps in the areas of applied science which support the Transformational Countermeasures Technologies Initiative (TCTI) of the CB Defense Program, and develop a web-based system for storage and access of CB M&S and IT development data and knowledge.</p>	4192	2686	10421	12919
Information Systems Technology, Sensor Data Fusion Hazard Prediction with Nowcasting (DTO CB62) -	2100	600	0	0

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Bullet Text (cont)	FY2006	FY2007	FY2008	FY2009
<p>FY 06 - Enhanced near-surface environmental characterization and demonstrated improvements using the Joint Effects Model (JEM). Published report from study of complex environments and algorithm refinement from previous years efforts. Assessed and selected methods for integrating near real-time weather data into transport and dispersion models. Enhanced interface between JEM and mesoscale models. Demonstrated CB prototype source determination modules. Initiated consolidation of source term determination module development. Developed and tested the Second-order Closure Integrated Puff (SCIPUFF) Adjoint Model using ideal observational data from field trials. Validated initial prototype and completed documentation. Continued development of preferred methods for using specific data from chemical and biological sensors to determine hazard source characteristics.</p> <p>FY 07 - Complete DTO CB62 as technology has been fully developed by other government and private entities. Publish final report and computational implementation of preferred algorithm(s) for source term estimation.</p>	2100	600	0	0
<p>Information Systems Technology, Sensor Data Fusion Hazard Prediction with Nowcasting -</p> <p>FY 07 - Leverage efforts from previous DTO work to initiate selection of most appropriate source term estimation tool(s) and develop Graphical User Interface (GUI) and Application Program Interface (API). Initiate hazard prediction refinement development based on accurate source term characterization and CB data assimilation. Develop a biological background model to reduce sensor false alarms in a realistic biological background. Test sensor placement optimization software suite against existent field data. Initiate indoor sensor data fusion effort. Collect field trial data for Validation and Verification (V&V) of sensor data fusion algorithms.</p> <p>FY 08 - Initiate validation of source term estimation and hazard refinement techniques against new high-resolution field trial data. Complete prototype algorithm for indoor sensor data fusion applications. Continue biological background model development to reduce sensor false alarms - delivery of first generation prototype. Initiate development of a sensor placement tool for optimal hazard prediction. Demonstrate formal adjoint of transport and dispersion model.</p>	0	1800	5671	4980
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Bullet Text (cont)	FY2006	FY2007	FY2008	FY2009
FY 09 - Complete biological background model development to reduce sensor false alarms - delivery of first generation prototype. Continue development of a sensor placement tool for optimal hazard prediction. Initiate development of capability to continuously refine and update contamination footprint thru rapid assimilation of limited and disparate information into meteorological and transport and dispersion models.	0	1800	5671	4980
Information Systems Technology, Battle Space Management - FY 06 - Piloted Net-Centric Enterprise Systems (NCES) modules for migration to test environment. Developed an end-to-end laboratory facility to test the requirements for integrating CBRN sensors onto existing and planned Command, Control, Communications, Computers, Intelligence, Surveillance, and Reconnaissance (C4ISR) networks. Conducted study of user interface requirement for future indications and warning for CBRN hazards in both deployed force and homeland defense scenarios. Developed integration strategy to link consequence management capability into Joint Warning and Reporting Network (JWARN). Initiated development of appropriate bridging capability to extend JWARN capabilities to homeland defense architectures. Initiated development of a modeling/exercise rehearsal capability for JWARN. Field-tested intelligent agent decision. Provided an integrated demonstration and user access for the Shared Common Operating Picture (COP). Conducted live real-time demonstration of JWARN Component Interface Device (JCID) compliant thin server on examples of fielded JWARN sensors. Continued work on web services, NCES and Global Information Grid (GIG) integration for common CBRN software services. Demonstrated inter-LAN socket connection manager in a simulated network environment.	6525	6250	2836	2990
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Bullet Text (cont)	FY2006	FY2007	FY2008	FY2009
<p>FY 07 - Build NCES modules for migration to test environment. Complete NCES service pilot. Cross-program reuse pilot in selected JPM-IS programs. Develop the CB-sensor network test facility. Develop certification lab capability for JWARN related sensors and nodes. Initiate test of CBRN interfaces to assess impact on JWARN and other C4ISR entities. Initiate preliminary research on alternative CBRN display technologies. Continue sensor-data fusion and source term location technologies with eventual integration with JEM and Joint Operational Effects Federation (JOEF). Develop the exchange and multi-level fusion of actionable information with real world C2 systems in DOD, Coalition and Homeland Security and Homeland Defense (HLS/HLD) domains. Support JCID development by modifying our existing Extensible Markup Language (XML) thin server for chemical sensors to meet JCID requirements and demonstrate its operation for JWARN.</p> <p>FY 08 - Continue research on alternative CBRN display technologies. Continue sensor-data fusion and source term location technologies with eventual integration with JEM and JOEF. Demonstrate the exchange and multi-level fusion of actionable information with real world C2 systems in DOD, Coalition and HLS/HLD domains. Transition modified XML thin server for chemical sensors to meet JCID requirements to JWARN. Transition the Inter-LAN Socket Connection Manager to JWARN.</p> <p>FY 09 - Develop next generation technologies and net-centric enterprise integration. Integrate Sensor Data Fusion (SDF) technologies into CB network. Initiate development of high speed data acquisition supporting full spectrum decision support for CB. Explore Nanotechnology solutions in support of Information Management Systems and the Transformational Countermeasure Technologies Initiative efforts.</p>	6525	6250	2836	2990
Information Systems Technology, Chemical and Biological Hazard Environment Prediction (DTO CB55) - FY 06 - Completed DTO CB55.	800	0	0	0
Information Systems Technology, Chemical and Biological Hazard Environment Prediction -	5945	4879	2836	1988

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Bullet Text (cont)	FY2006	FY2007	FY2008	FY2009
<p>FY 06 - Leveraged efforts from previous DTO work and continued high altitude and intentionally functioning missile intercept effects characterization by understanding and modeling key physics for single drops. Continued littoral and maritime effects research for JEM by improving boundary layer meteorological modeling capabilities. Conducted study of computation modeling for urban flows. Conducted study of Non-Traditional Agent (NTA) transport and dispersion module requirements for JEM. Conducted verification, validation and documentation of the knowledge based approach for intelligent sensor control and networking. Adapted and integrated existing cellular automata models into a Geographic Information System (GIS) tool for hazard assessment. Directed validation of FAST3D-CT model with wind tunnel data.</p> <p>FY 07 - Complete development of data assimilation techniques to improve forecasts of near-surface characteristics important for hazard prediction. Continue development of models for high altitude, urban, littoral and coastal environments, and indoor scenarios to be used by the JEM. Model key physics for large scale events for the high altitude intercept module. Provide validation procedures for urban contaminant transport models. Initiate validation of wind tunnel and FAST3D-CT with Oklahoma City Scale Model (OKC) field trial data. Publish FY07 validation report. Develop/integrate/test new Cellular Automata CBR specific models. Evaluate mesoscale model forecasts using available observations for improved coastal and urban dispersion predictions.</p> <p>FY 08 - Complete development of data assimilation techniques to improve forecasts of near-surface characteristics important for hazard prediction. Complete development of models for high altitude, urban, littoral and coastal environments, and indoor scenarios to be used by the JEM. Model key physics for large scale events for the high altitude intercept module. Provide validation procedures for urban contaminant transport models. Complete validation of wind tunnel and FAST3D-CT with urban field trial data. Publish FY08 validation report. Initiate development of advanced numerical weather prediction parameterizations and ensemble techniques.</p>	5945	4879	2836	1988

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Bullet Text (cont)	FY2006	FY2007	FY2008	FY2009
FY 09 - Complete development of variable resolution database containing highly refined estimates of "typical" atmospheric conditions for any given location and time. Expand and improve multi-scale four-dimensional data assimilation model. Continue development of waterborne transport model. Initiate optimization of methods to significantly improve performance of transport and dispersion hazard models for JEM.	5945	4879	2836	1988
Information Systems Technology, Chemical and Biological Warfare Effects on Operations - FY 06 - Identified new applications for the Joint Operational Effects Federation (JOEF). Implemented Mission-Oriented Protective Posture (MOPP) capabilities and integrated the biological agent toxicity model into the military worth assessment toolkit. Initiated development of an operational impact assessment tool. Initiated and completed the requirements generation for the linkage of the Simulated Training and Analysis for Fixed Facilities/Sites (STAFFS) and contamination models. Initiated model design and development of Chemical-Improvised Explosive Device (C-IED) effects model. Conducted a side-by-side comparison of mobile force models for inclusion in JOEF. Improved CBR operational effects modeling tools and methods by working with various agencies/labs to identify capabilities and areas for follow-on research/development. Initiated development activities for the integration of JOEF components with theater-level models such as the Joint Integrated Contingency Model (JICM). Continued design methods for new operational and threat domains; implemented conventional, radiological methodologies, developed data collection plan for supporting database for Next Generation Model of CB Effects on Military Operations. Modeled two mission examples (e.g. Aerial Port of Debarkation and Sea Port of Debarkation), and developed initial Rapid Mission Impact Assessment Tool based on example missions. Conducted a Web-services and data model study and initial implementation of IMPACT framework.	9046	9433	3781	3986
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BUDGET ACTIVITY RDT&E DEFENSE-WIDE/ BA2 - Applied Research	PE NUMBER AND TITLE 0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)		PROJECT CB2	
Bullet Text (cont)	FY2006	FY2007	FY2008	FY2009
<p>FY 07 - Integrate mobile forces modules. Continue developing integration with theater-level models and begin initial testing with Joint Forces Command (JFCOM) and other selected Combatant Commands (COCOMs). Build plan for developing a complete virtual environment training capability. Demonstrate proof-of-concept for the Chemical-Improved Explosive Device (C-IED) model. Demonstrate applicability of the automated CBRN data import/export tool. Implement new operational models. Develop methods for human-in-the-loop and automated analysis capability. Conduct a prototype development and proof-of-concept demonstration for the improved CBRN situational awareness methodology. Enhance software and conduct additional tests on the rapid mission impact assessment tool. Complete the STAFFS and contamination model linkages. Test and verify software upgrades. Implement new operational models; operational tests and exercise participation, and develop methods for human-in-the-loop and automated analysis for Next Generation Model of CB Effects on Military Operations. Enhance Rapid Mission Impact Assessment Tool and test on additional missions. Implement aggregation methodology for CBRN in Tactical and Theatre Level Simulation Model and begin linking to tactical model. Implement web-services interface and data model for IMPACT framework. Determine preliminary applications in military exercises for Decision Support for Logistics Response to CBR Attacks model.</p> <p>FY 08 - Implement new models for Next Generation Model of CB Effects on Military Operations. Complete link with tactical model of CBRN in Tactical and Theatre Level Simulation Model and begin link with theatre model. Provide architectural enhancements and implementation of initial linkages for IMPACT framework. Refine design and expand methodology development for improving CBRN situational awareness. Perform integrated software/system tests on Decision Support for Logistics Response to CBR Attacks model.</p> <p>FY 09 - Demonstrate IMPACT Framework linkage methodology and architectural enhancements. Develop documentation for Methodology for Improving CBRN Situational Awareness. Transition Decision Support for Logistics Response to CBR Attacks to Global Command and Control System and Global Combatant Support System (GCCS/GCSS).</p>	9046	9433	3781	3986
Total	28608	25648	25545	26863
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	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>
Decontamination	7023	6836	7309	0

Accomplishments/Planned Program	FY2006	FY2007	FY2008	FY2009
<p>Decontamination, Solution Chemistry -</p> <p>FY 06 - Concluded development of a chlorine dioxide based man-portable decontamination system and investigated alternative solution based technologies for developing chlorine dioxide to support the Joint Portable Decontamination System (JPDS); continued efforts to develop reactive impregnated peracetate solvent-based wiping system capable of decontaminating vehicle interiors and sensitive equipment to support Joint Service Sensitive Equipment Decontamination (JSSED) and Joint Platform Interior Decontamination (JPID).</p> <p>FY 07 - Complete chamber testing on chlorine dioxide-based candidates and transition to JPDS. Initiate research on technologies to develop hydrogen peroxide at their point-of-use.</p> <p>FY 08 - Complete research and publish findings on technologies to develop hydrogen peroxide at their point-of-use.</p>	3033	1685	2500	0

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Accomplishments/Planned Program (Cont):	FY2006	FY2007	FY2008	FY2009
<p>Decontamination, Solid Phase - FY 06 - Continued development of porous polymer solvent cartridges for removing CW agents from fluorinated solvent used in sensitive equipment decontamination as a JSSED incremental improvement.</p> <p>FY 07 - Complete development of an improved filtration system for hydrofluoro ethers solvent cleaning systems and transition to the JSSED program as a product improvement. Initiate new research to develop reactive sorbent nano-active suspensions and sprayable powders for Joint Service Transportable Decontamination System (JSTDS) - Small Scale (SS) including modifications of the technologies for decontamination in extreme weather conditions.</p> <p>FY 08 - Complete efforts to develop reactive sorbent nano-active suspensions and sprayable powders for JSTDS and consolidate efforts under Protection capability area in FY 2009.</p>	696	1326	1250	0
<p>Decontamination, Alternative Process - FY 06 - Initiated research to determine and develop efficacy of a gaseous chemical and biological decontamination system combining hot air and modified vaporous hydrogen peroxide. Transitioned efficacy findings to BA3 to support the JPID, JSTDS and JSSED programs. Initiated new studies to determine technical potential of reactive coatings.</p> <p>FY 07 - Complete research on gaseous decontamination system modifications for decontamination in extreme weather conditions. Initiate research to demonstrate alternative decontamination processes using gas, kinetic, energetic, and/or novel approaches to support the Transformational Countermeasures Technologies Initiative (TCTI) approach.</p> <p>FY 08 - Continue to investigate novel approaches to develop new decontamination processes based on the TCTI approach and consolidate effort under Protection capability area in FY 2009.</p>	2179	1919	2349	0
<p>Project CB2/Line No: 014</p> <p align="center">Page 18 of 83 Pages</p> <p align="right">Exhibit R-2a (PE 0602384BP)</p>				

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Accomplishments/Planned Program (Cont):	FY2006	FY2007	FY2008	FY2009
<p>Decontamination, Process Fundamentals -</p> <p>FY 06 - Initiated research efforts to develop an aerosol-based decontamination application and determined the efficacy effects using aerosolized activated hydrogen peroxide. Continued research into methodology for the metal catalyzed alcoholysis of neutral organophosphates and organophosphates, including chemical G- and V-agents under neutral conditions and ambient temperature.</p> <p>FY 07 - Complete research into methodology for the metal catalyzed alcoholysis of neutral organophosphates and organophosphates, including chemical G- and V-agents under neutral conditions and ambient temperature. Continue research efforts to develop an aerosol-based decontamination application and determine the efficacy effects using aerosolized activated hydrogen peroxide. Continue development of a decontamination assurance spray that was initiated as part of Small Business Innovative Research (SBIR), and initiate research to determine the effect of droplet sized decontaminant on the efficacy of aerosolized peroxy-based decontaminants.</p> <p>FY 08 - Complete research efforts to develop an aerosol-based decontamination application and determine the efficacy effects using aerosolized activated hydrogen peroxide. Complete research to determine the effect of droplet sized decontaminant on the efficacy of aerosolized peroxy-based decontaminants.</p>	1115	1906	1210	0
Total	7023	6836	7309	0

	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>
Detection	19588	22134	34118	34299

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Accomplishments/Planned Program	FY2006	FY2007	FY2008	FY2009
<p>Point Detection, Integrated CB -</p> <p>FY 06 - Continued feasibility assessment of first generation breadboard based on millimeter wave spectroscopy for bio detection. Continued Raman spectroscopy for the detection/identification of biological materials. Initiated investigations in solid state visible and UV receivers to replace photomultiplier tube for improved size, weight, power, reliability, and cost. Initiated microelectronic machine sized solid state Fourier Transform Infrared (FTIR) point sensor system.</p> <p>FY 07 - Continue feasibility assessment of first generation breadboard based on millimeter wave spectroscopy for biological detection. Complete Raman spectroscopy for the detection/identification of biological materials. Complete investigations in solid state visible and UV receivers to replace photomultiplier tube for improved size, weight, power, reliability, and cost. Continue microelectronic machine sized solid state FTIR point sensor system. Initiate feasibility studies on assays for biological materials based on multiphoton, multi-wavelength processes. Initiate development of novel use of laser technology to separate biological materials for enhanced detection of biological warfare agents in water. Initiate development of novel laser sources and evaluation of discrimination capability and optical design aspects for BW aerosol detection with these sources. Initiate feasibility studies on the use of novel nanowire-array sensors for enhanced sensitivity and selectivity in the detection of biological warfare materials.</p> <p>FY 08 - Complete feasibility assessment of first generation breadboard based on millimeter wave spectroscopy for biological detection. Complete microelectronic machine sized solid state FTIR point sensor system. Continue feasibility studies on assays for biological materials based on multiphoton, multi-wavelength processes. Continue development of novel use of laser technology to separate biological materials for enhanced detection of biological warfare agents in water. Continue development of novel laser sources and evaluation of discrimination capability and optical design aspects for BW aerosol detection with these sources. Continue feasibility studies on the use of novel nanowire-array sensors for enhanced sensitivity and selectivity in the detection of biological warfare materials. Initiate feasibility study into nanoscale detection systems to meet the Transformational Countermeasures Technology Initiative (TCTI).</p>	4075	5864	6000	7299

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Bullet Text (cont)			FY2006	FY2007
<p>FY 09 - Complete feasibility studies on assays for biological materials based on multiphoton, multi-wavelength processes. Complete development of novel use of laser technology to separate biological materials for enhanced detection of biological warfare agents in water. Complete development of novel laser sources and evaluation of discrimination capability and optical design aspects for BW aerosol detection with these sources. Complete feasibility studies on the use of novel nanowire-array sensors for enhanced sensitivity and selectivity in the detection of biological warfare materials. Continue feasibility study into nanoscale detection systems to meet the TCTI.</p>			4075	5864
<p>Detection, Biological and Chemical Stand-off Technology -</p> <p>FY 06 - Initiated the development of models to predict passive standoff technology responses to aerosols. Initiated detection modalities to detect sentinel species from biological chemical warfare materials and processes. Initiated studies to investigate the optimal performance parameters for hyperspectral technology to detect biological materials.</p> <p>FY 07 - Continue the development of models to predict passive standoff technology responses to aerosols. Continue the study on the detection modalities to detect sentinel species from biological chemical warfare materials and processes. Continue the studies to investigate the optimal performance parameters for hyperspectral technology to detect biological materials. Continue studies to optimize/convert detection algorithms to imaging technology. Initiate validation and modeling studies to increase the level of discrimination of biological materials in the IR electromagnetic spectral regions based upon DISC/DIAL and polarization spectra techniques.</p>			2883	3270
			6000	7299
			5000	0

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BUDGET ACTIVITY RD&E DEFENSE-WIDE/ BA2 - Applied Research	PE NUMBER AND TITLE 0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	PROJECT CB2
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Bullet Text (cont)	FY2006	FY2007	FY2008	FY2009
FY 08 - Complete models to predict passive standoff technology responses to aerosols. Continue the study on the detection modalities to detect sentinel species from biological chemical warfare materials and processes. Complete studies to investigate the optimal performance parameters for hyperspectral technology to detect biological materials. Complete studies to optimize/convert detection algorithms to imaging technology. Complete and transition validation and modeling studies on the level of discrimination of biological materials in the IR electromagnetic spectral regions based upon adsorption, scattering, and polarization spectra techniques to the Joint Biological Standoff Detection System (JBSDS) Increment 2.	2883	3270	5000	0

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Accomplishments/Planned Program (Cont):	FY2006	FY2007	FY2008	FY2009
<p>Detection of CB Contamination on Surfaces -</p> <p>FY 06 - Initiated the development of technology to meet the needs to detect contamination on surfaces in a post decontamination application; focused primarily on chemicals at a sensitivity of 10 mg/m2 level of contamination. Initiated efforts on off-gassing techniques for increased sensitivity of current Raman based Laser Interrogation of Surface for Agents (LISA) system.</p> <p>FY 07 - Continue the development of technology to meet the needs to detect contamination on surfaces in a post decontamination application. Initiate feasibility studies on post-decontamination verification using standoff detection methodology other than Raman based LISA.</p> <p>FY 08 - Continue the development of technology to meet the needs to detect contamination on surfaces in a post decontamination application. Complete efforts using off-gassing techniques and Raman based LISA. Complete feasibility studies on post-decontamination verification using standoff detection methodology.</p> <p>FY 09 - Continue the development of technology to meet the needs to detect contamination on surfaces in a post decontamination application. Evaluate and assess technology for down-selection from non-Raman optical standoff techniques vs. Raman based LISA vs off-gassing techniques for brassboard design.</p>	1900	4000	6000	7000

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Accomplishments/Planned Program (Cont):	FY2006	FY2007	FY2008	FY2009
<p>Point Detection, Biological Identification -</p> <p>FY 06 - Leveraged efforts from medical science and technology programs in proteomics for biomarkers for the identification of biological agents in complex biological backgrounds.</p> <p>FY 07 - Initiate development of portable technology to completely sequence entire pathogen genomes based upon the sequencing thru synthesis concept. This technology is being leveraged from National Institute of Health efforts to reduce cost at their genomic centers.</p> <p>FY 08 - Continue development of portable technology to completely sequence entire pathogen genomes based upon the sequencing thru synthesis concept. Complete breadboard design and initiate build of prototype system and transition to BA3.</p> <p>FY 09 - Complete development and demonstrate portable technology to completely sequence entire pathogen genomes.</p>	2030	4000	10000	10000
<p>Detection, Wide-Area Aerial Reconnaissance for Chemical Agents (DTO CB53) -</p> <p>FY 06 - Determined optimum spectrometer performance specifications in terms of scan speed, spatial resolution, and spectral resolution. Demonstrated an enhanced FTIR and tunable IR systems with real-time data processing on an airborne platform in a reconnaissance application using the appropriate performance parameters. Completed DTO. This DTO supported the Joint Nuclear Biological Chemical Reconnaissance System (JNBCRS) program.</p>	4000	0	0	0

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Accomplishments/Planned Program (Cont):	FY2006	FY2007	FY2008	FY2009
<p>Point Detection, Chemical -</p> <p>FY 07 - Initiate transition of technology from Defense Advanced Research Projects Agency (DARPA) on the development of a micro gas analyzer (MGA) based on MEMS technology. Focus is on real-time (less than 5 sec) detection/identification of sub miosis sensitivity levels (parts per trillion) and the expansion of the number of detectable materials to include the high priority Toxic Industrial Chemicals (TICs).</p> <p>FY 08 - Complete transition of MGA technology from DARPA. Initiate development of MGA technology as the replacement technology for the Joint Chemical Agent Detector or for integration into other Major Defense Acquisition platforms requiring chemical warfare agent detection.</p> <p>FY 09 - Continue development of MGA technology as the replacement technology for the Joint Chemical Agent Detector or for integration into other Major Defense Acquisition platforms requiring chemical warfare agent detection.</p>	0	5000	7118	10000
<p>Stand-off Biological Aerosol Detection (DTO CB35) -</p> <p>FY 06 - Demonstrated the optimized system performance to detect and discriminate biological agents with at least a sensitivity of 1,000 agent containing particles per liter of air (ACPLA) at a range of 1 km with an objective false alarm rate no more than one per week in both daytime and nighttime operations. Evaluated the feasibility of the demonstrated technology to also meet the chemical stand-off detection requirements. Completed DTO in FY06 and effort supports the Joint Biological Stand-off Detection Systems (JBSDS).</p>	4700	0	0	0
Total	19588	22134	34118	34299

	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>
Protection	10391	11337	22962	28401

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Accomplishments/Planned Program	FY2006	FY2007	FY2008	FY2009
<p>Protection, Percutaneous Protection, Reduced Physiological Burden -</p> <p>FY 06 - Completed development of the Pulsed Microclimate Cooling System (PMCS) that demonstrated a 40 percent energy savings thru human physiological testing and transitioned results to Army Technology Objective (ATO[R] NSC-03) Soldier Borne Microclimate Cooling Technologies and other programs for further development. Demonstrated selective and responsive nanopore-filled membranes synthesis concept, and encapsulated nanofiber mesh membranes fabrication. Measured permeability response of concept membranes as a function of electrical stimuli. Synthesized polymers and blends for application in elastomeric permselective membranes, evaluated water vapor and stimulant permeation, and modeled polymer molecular dynamics. Resulting technologies support the Ground Soldier System for Future Combat System.</p> <p>FY 07 - Initiate work to develop a processable interpenetrating polymer network comprising of a soft breathable passive network interspersed with a conducting polymer network whose permeability properties can be electrically controlled. Develop elastic, conformable CB protective fabrics with selectively permeable properties for advanced warfighting ensembles. Optimize polymers and blends for application in elastomeric permselective membranes, characterize their permeation characteristics, and evaluate their physical properties. Produce fabric laminates for laboratory evaluation. Technologies support future protective ensembles. Restructure efforts for enhanced protection into the development of an integrated CB protective fabric that incorporates elements of previous efforts on enhanced percutaneous protection (aerosol Non-Traditional Agents (NTA), biological agents, liquid NTAs, and Toxic Industrial Chemicals(TICs)) and self-detoxifying materials into a single integrated effort. For FY 2008, this effort will be titled "Individual Protection, Integrated Protective Fabric" and combines Integrated Protective Fabrics Enhanced Protection and Reduced Burden.</p>	1010	900	0	0
Individual Protection, Percutaneous Protection, Enhanced Protection (Aerosol NTAs and Bio) -	1505	1100	0	0

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Bullet Text (cont)	FY2006	FY2007	FY2008	FY2009
<p>FY 06 - Down-selected aerosol barrier materials and closure concepts, incorporated both into an initial prototype garment, and evaluated. Optimized materials, closures, and suit design based on results of the evaluation. Characterized Individual Protection Equipment (IPE) materials filter efficiency for particle sizes and wind speeds, assessed effect of material geometry on filter efficiency, and correlated challenge deposition in IPE systems with swatch, component tests at elevated wind speeds. Developed lab-scale non-woven polymer membrane samples and evaluated to assess particle removal efficiency and air permeability. Resulting technologies/knowledge transitioned to an integrated fabric development project in support the Ground Soldier System for Future Combat System. Transitioned elevated wind speed agent effects characterization to standard methodology development efforts that will support test range capability development.</p> <p>FY 07 - Produce and evaluate an optimized second-generation prototype garment employing both aerosol barrier materials and advanced closures. Develop one square meter non-woven polymer membranes material, incorporate into a prototype fabric system and assess performance. Restructure efforts for enhanced protection into the development of an integrated CB protective fabric that incorporates elements of previous efforts on enhanced percutaneous protection (aerosol NTA, biological agents, liquid NTAs, and TICs) and self-detoxifying materials into a single integrated effort. For FY 2008, this effort will be titled "Individual Protection, Integrated Protective Fabric" and combines Integrated Protective Fabrics Enhanced Protection and Reduced Burden.</p>	1505	1100	0	0
<p>Individual Protection, Percutaneous Protection, Enhanced Protection (Liquid NTAs and TICs) -</p> <p>FY 06 - Identified candidate fibers as support structures for sorbents and reactives and initiated laboratory evaluation of prototype fabrics to assess physical and permeation characteristics. Conducted market research to identify innovative materials applicable to protective boots and gloves, and identified candidates for further consideration. Resulting technologies/knowledge transitioned to an integrated fabric development project in support the Ground Soldier System for Future Combat System, and Joint Chemical Ensemble (JCE).</p>	379	1250	0	0
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Bullet Text (cont)				
	FY2006	FY2007	FY2008	FY2009
FY 07 - Based on FY06 evaluations, optimize novel fiber/fabrics and conduct fabric characterization and simulant permeation testing. Conduct preliminary physical and chemical testing of candidate materials for glove and boot applications. Restructure efforts for enhanced protection into the development of an integrated CB protective fabric that incorporates elements of previous efforts on enhanced percutaneous protection (aerosol NTA, biological agents, liquid NTAs, and TICs) and self-detoxifying materials into a single integrated effort. For FY 08, this effort will be titled "Individual Protection, Integrated Protective Fabric" and combines Integrated Protective Fabrics Enhanced Protection and Reduced Burden.	379	1250	0	0
Individual Protection, Integrated Protective Fabric - FY 08 - Complete work on identifying and assessing nanocatalytic and nano-particle reactive materials with detoxifying and anti-microbial properties and down-selecting candidate materials. Continue development of test methodologies. Continue the development of elastic, conformable CB protective fabrics with selectively permeable properties. Continue development of processable interpenetrating polymer networks whose permeability properties can be electrically controlled. Initiate work on fabric residual life indicators. Initiate selection and development of novel sorbents leap-ahead improvements over activated carbon technologies. Initiate development and selection of ultralight and tactile barrier materials for gloves and boots. Continue fabrication and testing of prototype integrated fabrics to determine protection, mechanical properties, and heat transfer characteristics. Continue use of computational methods for assessment and refinement of prototypes. Initiate ensemble design conceptual work based on lessons gathered in the human performance project. Resulting technologies/knowledge will transition to an integrated fabric development project in support of the Ground Soldier System for Future Combat System, and JCE.	0	0	5800	5800
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Bullet Text (cont)	FY2006	FY2007	FY2008	FY2009
FY 09 - Complete development of test methodologies. Continue the development of elastic, conformable CB protective fabrics with selectively permeable properties. Continue development of processable interpenetrating polymer networks whose permeability properties can be electrically controlled. Continue work on fabric residual life indicators that can be automatically integrated. Continue development of novel sorbents leap-ahead improvements over activated carbon technologies. Complete development work on ultra light and tactile barrier materials for gloves and boots. Continue fabrication and testing of prototype integrated fabrics to determine protection, mechanical properties, and heat transfer characteristics. Continue use of computational methods for assessment and refinement of prototypes. Continue ensemble design conceptual work based on lessons gathered in the human performance project. Initiate fabrication of prototype ensembles for evaluation and demonstration. Resulting technologies/knowledge will transition to an integrated fabric development project in support of the Ground Soldier System for Future Combat System, and JCE.	0	0	5800	5800
Individual Protection, Human Performance - FY 08 - Continue the comprehensive study to reduce physiological burden on the human performance parameters for various warfighter subgroups in the performance of their mission when CB protective systems are employed. Identify trade space between physiological and psychological comfort with regards to warfighter effectiveness. Initiate work to develop an overall comfort and performance model for CB protective equipment. Continue human subject studies on effects of breathing resistance at high work rates. Develop a human response model for breathing rates and assistance. FY 09 - Complete the comprehensive study to reduce physiological burden on the human performance parameters for various warfighter subgroups in the performance of their mission when CB protective systems are employed. Publish findings on trade space between physiological and psychological comfort with regards to warfighter effectiveness. Continue work to develop an overall comfort and performance model for CB protective equipment. Complete human subject studies on the effects of breathing resistance at high work rates. Develop a draft standard for Air Purifying Respirator (APR) qualification. Transition results into the comfort and performance model.	0	0	2902	2851
Individual Protection, Self-Decontaminating Processes -	0	0	0	6360
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Bullet Text (cont)	FY2006	FY2007	FY2008	FY2009
FY 09 - Continue efforts from FY 08 Decontamination Alternative Processes and Solid Phase to develop self decontaminating processes using the Transformational Countermeasure Technologies Initiative (TCTI) approach.	0	0	0	6360
<p>Respiratory Protection, Enhanced CBRN/NTA/TIC Protection -</p> <p>FY 06 - Completed a trade-off analysis and initiated fabrication of advanced mask concept prototype models. Down-selected the most promising technologies for protection enhancement. This included intelligent seals, micro-thermoelectric system for cooling, and active air management systems for comfort and protection. Conducted research on a dual-cavity sealing system for insertion into the selected mask platform. The trade-off analysis resulted in two new start efforts in FY 07 for Individual Protection: Respiratory/Ocular Protection and Air Purification.</p> <p>FY 07 - Initiate Individual Protection, Respiratory/Ocular Protection projects. Initiate the investigation of intelligent seal enhancement materials and technologies that will provide improvements in the field protection factor performance and comfort of a respirator. Define the key development parameters associated with respiratory protective systems and analyze advanced concept options based on these parameters by establishing geometric relationships with operational performance. Continue to develop a dual-cavity respirator with increased levels of respiratory protection that provide a real-time indication of mask fit. Initiate project to develop the next generation filter for individual protection with objective of decreasing weight and breathing resistance, reducing the profile, and increasing protection against TICs. Continue to develop metal-organic frameworks as turnable sorbents for advance air purification technologies in protective masks. Initiate development of a process to grow alumina nanofiber on a silica matrix to optimize size and density of nanofibers.</p>	1710	1826	6710	5850

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Bullet Text (cont)	FY2006	FY2007	FY2008	FY2009
<p>FY 08 - Initiate the integration of the protective mask designs with developmental helmet systems to provide seamless compatibility of CB protection with ballistic protection and integration of communication and optical systems. Continue the investigation of intelligent seal enhancement materials and technologies that will provide improvements in the field protection factor performance and comfort of a respirator. Continue to define the key development parameters associated with respiratory protective systems and incorporate data and lessons from the human performance project. Continue to develop a dual-cavity respirator with increased levels of respiratory protection that provide a real-time indication of mask fit. Continue project to develop the next generation filter for individual protection. Continue to develop metal-organic frameworks as turnable sorbents for advanced air purification technologies in protective masks. Initiate the development of nanofiber-based filters with high efficiency, reduced pressure drop and reduction in weight and cube. Continue development of a process to grow alumina nanofiber on a silica matrix to optimize size and density of nanofibers. Initiate effort to develop a sorptive and reactive capacity residual life indicator for mask filters. Initiate reactive hybrid approaches for individual protection filtration.</p> <p>FY 09 - Complete integration of the protective mask designs with developmental helmet systems to provide seamless compatibility of CB protection with ballistic protection and integration of communication and optical systems. Complete the investigation of intelligent seal enhancement materials and technologies that will provide improvements in the field protection factor performance and comfort of a respirator. Continue to define the key development parameters associated with respiratory protective systems and incorporate data and lessons from the human performance project. Complete work on the dual-cavity respirator with increased levels of respiratory protection that provide a real-time indication of mask fit and integrate concept into the final design. Continue project to develop the next generation filter for individual protection. Complete development of metal-organic frameworks as turnable sorbents for advance air purification technologies in protective masks. Complete the down-selection of ceramic and polymer nanofiber-based filters. Continue reactive hybrid approaches for individual protection filtration. Develop and fabricate initial prototypes and evaluate performance.</p>	1710	1826	6710	5850
Project CB2/Line No: 014	Page 31 of 83 Pages		Exhibit R-2a (PE 0602384BP)	

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BUDGET ACTIVITY RDT&E DEFENSE-WIDE/ BA2 - Applied Research	PE NUMBER AND TITLE 0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	PROJECT CB2
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Accomplishments/Planned Program (Cont):	FY2006	FY2007	FY2008	FY2009
<p>Protection, Advanced Air Purification System Model (DTO CB61) -</p> <p>FY 06 - Configured laboratory-scale systems, defined test and evaluation methodology, and measured the required design and system integration data (characterize unit processes). Determined parameters for an Advanced Air Purification System Model.</p> <p>FY 07 - Develop several potential system configuration designs. Complete work on a trade study tool for the optimization, sensitivity analysis, and assessment of Advanced Air Purification (AAP) systems. Define standard AAP test methods and procedures. Support AAP demonstration programs (design review, requirements review, test plan) and incorporate demonstration data into AAP database. Optimize the demonstration to best meet the intended application's requirements. Close a critical data gap by linking full scale simulant results to lab scale simulant and agent results. Characterize chemical performance of the demonstrator at untested conditions. Characterize scaling properties and integration sensitivities of demonstrator. Verify agent performance at full scale and provide data to AAP model required to estimate agent performance. Complete DTO and transition the Air Purification Evaluation Tool to Overarching Collective Protection (COLPRO) Model.</p>	700	500	0	0

<p>Project CB2/Line No: 014</p> <p align="center">Page 32 of 83 Pages</p> <p align="right">Exhibit R-2a (PE 0602384BP)</p>
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BUDGET ACTIVITY RDT&E DEFENSE-WIDE/ BA2 - Applied Research	PE NUMBER AND TITLE 0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	PROJECT CB2
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Accomplishments/Planned Program (Cont):	FY2006	FY2007	FY2008	FY2009
<p>Protection, Improved Single-Pass Filters -</p> <p>FY 06 - Continued work to identify broad spectrum sorbents for application in both single pass and regenerative filtration systems for removal of Toxic Industrial Chemicals (TIC) and other problematic chemicals. Developed chemical probes, hardware and methodology to assess residual life indicator COLPRO chemical filters. Assessed and reported the impact of particle size distribution and long-term loading by measuring efficiency changes on aerosol/particulate flat sheet High Efficiency Particulate Arrestance (HEPA) media and full size HEPA filters.</p> <p>FY 07 - Investigate adding ethylene oxide, nitrogen dioxide and carbon monoxide functionalities to CP filters. Transition results of investigations on polishing sorbent technology Pressure Swing Adsorption (PSA), Temperature Swing Adsorption (TSA) and Pressure/Temperature Swing Adsorption (P/TSA) to JPM ColPro. Complete sorbent work on enhanced performance of single-pass filters and regenerative systems and transition data to DTO CB61. Resulting technologies/knowledge transitioned to an integrated fabric development project in support the Ground Soldier System for Future Combat System. Initiate the development of a highly efficient particulate filter that uses charged sub-micron water droplets and transition effort to Novel Air Purification Technologies.</p>	1042	900	0	0

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BUDGET ACTIVITY RDT&E DEFENSE-WIDE/ BA2 - Applied Research	PE NUMBER AND TITLE 0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	PROJECT CB2
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Accomplishments/Planned Program (Cont):	FY2006	FY2007	FY2008	FY2009
<p>Protection, Novel Air Purification Technologies -</p> <p>FY 08 - Initiate a project to develop energetic, reactive, media-less, and air purification technologies that reduce size, weight, and lifecycle costs of removing Chemical and Biological agents and Toxic Industrial Chemicals (TICs) from both make-up and recirculation air in buildings, shelters or platforms. Initiate development of an acoustic fractionator that removes particulates down to the submicron level using standing sound waves. Initiate development of a hybrid plasma filter that provides both vapor particulate removal and destruction capabilities. Initiate development of a new air purification technology based on selective ionization and contaminant extraction. Initiate development of a novel, low pressure drop, High Efficiency Particulate Arrestance (HEPA) filter, which provides increased dust capacity and extended filter life thru the use of irregularly shaped high surface area submicron fibers. Continue development of a highly efficient particulate filter that uses charged sub-micron water droplets from efforts under Improved Single-Pass Filters.</p> <p>FY 09 - Continue to develop energetic, reactive, media-less, and air purification technologies that reduce size, weight, and lifecycle costs of removing Chemical and Biological agents and TICs from both make-up and recirculation air in buildings, shelters, or platforms. Continue development of an acoustic fractionator that removes particulates down to the submicron level using standing sound waves. Continue development of a hybrid plasma filter that provides both vapor particulate removal and destruction capabilities. Continue development of a new air purification technology based on selective ionization and contaminant extraction. Continue development of a novel, low pressure drop, HEPA filter, which provides increased dust capacity and extended filter life thru the use of irregularly shaped high surface area submicron fibers. Complete demonstration of a highly efficient media less particulate filter that uses charged sub-micron water droplets. Down-select among technological approaches.</p>	0	0	3900	3900

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BUDGET ACTIVITY RDT&E DEFENSE-WIDE/ BA2 - Applied Research		PE NUMBER AND TITLE 0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)		PROJECT CB2	
Accomplishments/Planned Program (Cont):		FY2006	FY2007	FY2008	FY2009
<p>Protection, Regenerative and Reactive Air Purification - FY 06 - Performed lab-scale studies of two and four bed Temperature, Pressure, and Electrical Swing Adsorption (ESA) regenerative air purification systems. Initiated new evaluations of three competing Electrical Swing Adsorption technologies by constructing equivalent test stands. Applied temperature and pressure regenerative system technology from this effort to DTO CB61. Initiated new development of reactive air purification technologies.</p> <p>FY 07 - Optimize Temperature Swing Adsorption (TSA) and ESA operating parameters, adsorber design and test. Demonstrate air purification system based on selective ionization and contaminant extraction technology. Continue development of Reactive Air Purification technologies and transition to COLPRO System Integration in FY 2008.</p>		1385	1926	0	0
<p>Protection, Shelter Systems and Contamination Control Area (CCA)/Airlock/Toxic Free Area (TFA) (CCA/A/TFA) - FY 06 - Completed study that advanced and integrated collective protection shelter system technologies for airlocks, CB closures, CB barriers (impermeable and permeable reactive) and seaming. Convened working group to analyze threat, systems and current protocol; performed initial Computational Fluid Dynamics (CFD) airflow analysis, testing and generated interim report detailing CCA/A/TFA processing.</p> <p>FY 07 - Identify novel technologies for application in the CCA/A/TFA and develop initial CATFA processing system design and transition to COLPRO System Integration in FY 2008.</p>		1375	1770	0	0
<p>Protection, Shelter Materials, Coatings and Materials Treatments, Reactive or Self-Decontaminating - FY 06 - Continued development of CB barrier material for CB shelters. Continued the development of expedient protective coatings, determined material interactions and permeability and performed conceptual soft shelter testing. Developed a family of coatings that form a gas impermeable film for expedient encapsulation and CB hardening of existing structures. Initiated new development of microcrystalline and nanocrystalline cellulose materials for use with reactive chemistries.</p>		1285	1165	0	0
Project CB2/Line No: 014		Page 35 of 83 Pages		Exhibit R-2a (PE 0602384BP)	

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Bullet Text (cont)				
	FY2006	FY2007	FY2008	FY2009
FY 07 - Perform laboratory demonstration of coatings that will form a gas impermeable film for expedient encapsulation and CB hardening of existing structures. Perform vapor challenge with integrated shelter system components. Perform casting of barrier films upon hard & soft substrates and perform simulant permeability testing of microcrystalline and nanocrystalline cellulose barrier films and transition to COLPRO System Integration in FY 08.	1285	1165	0	0
Protection, COLPRO System Integration - FY 08 - This effort transitions technologies from previous efforts of Regenerative and Reactive Air Purification, Shelter Systems and Contamination Control Area (CCA)/Airlock/Toxic Free Area, and Shelter Materials, Coatings and Materials Treatments, Reactive or Self-Decontaminating. Continue project to investigate alternate system solutions for Collective Protection (COLPRO). Expand study of system and alternatives and initiate efforts addressing specific technological gaps to facility development. Technologies may include, but will not be limited to, micro fine detoxifying aerosol fogs to facility entry and mitigate internal releases, internal self-detoxifying surfaces for walls and ductwork, expedient retrofit kits, self-detoxifying and expedient strippable coatings, rapid isolation and purge schemes, and novel an innovative air flow and recirculation schemes. FY 09 - Continue project to investigate alternate system solutions for COLPRO. Expand study of system alternatives and initiate efforts addressing specific technological gaps to facility development. Technologies may include, but will not be limited to, micro fine detoxifying aerosol fogs to facility entry and mitigate internal releases, internal self-detoxifying surfaces for walls and ductwork, expedient retrofit kits, self-detoxifying and expedient strippable coatings, rapid isolation and purge schemes, and novel and innovative air flow and recirculation schemes.	0	0	3650	3640
Total	10391	11337	22962	28401
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	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>
Threat Agent Sciences	29460	35751	24810	24307

Accomplishments/Planned Program	FY2006	FY2007	FY2008	FY2009
<p>Threat Agent Sciences, Agent Characterization and Simulant Development -</p> <p>FY 06 - Continued research into Non Traditional Agents (NTA) chemistry, characterizing synthetic pathways and NTA products, and developing NTA simulants. Initiated simulant and methodology development projects to address requirements in programs of record, as aligned by the CBDP Test and Evaluation (T&E) community.</p> <p>FY 07 - Continue research into NTA chemistry, characterizing synthetic pathways and NTA products, and developing NTA simulants. Continue simulant and methodology development projects to address requirements in programs of record, as aligned by the T&E community. Initiate simulant correlation studies to define operational envelopes in which simulants may be used for Developmental Tests and Operation Tests (DT/OT).</p> <p>FY 08 - Continue research into NTA chemistry, characterizing synthetic pathways and NTA products, and developing NTA simulants. Continue simulant and methodology development projects to address requirements in programs of record, as aligned by the T&E community. Continue simulant correlation studies to define operational envelopes in which simulants may be used for DT/OT.</p>	3718	4575	5937	5844

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BUDGET ACTIVITY RDT&E DEFENSE-WIDE/ BA2 - Applied Research	PE NUMBER AND TITLE 0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)		PROJECT CB2	
Bullet Text (cont)	FY2006	FY2007	FY2008	FY2009
FY 09 - Continue research into NTA chemistry, characterizing synthetic pathways and NTA products, and developing NTA simulants. Incorporate newly prioritized agents as identified by intelligence community and operational users. Continue simulant and methodology development projects to address requirements in programs of record, as aligned by the T&E community. Continue simulant correlation studies to define operational envelopes in which simulants may be used for DT/OT. Transition capabilities from Computation Chemistry programs to provide simulant design and selection methodologies for use in Operational Test and Evaluation.	3718	4575	5937	5844
Threat Agent Sciences, Agent Fate Biological Toxin Fate in Water Matrices - FY 06 - Completed the measurement of persistence (viability) of biological warfare agents released into operational environments.	664	0	0	0
Threat Agent Sciences, Low Level Toxicology, Low Level Chemical Warfare Agent Exposure Effects and Countermeasures (DTO CB51) - FY 06 - Conducted validation studies for predictive models that refine and extend the ability to extrapolate to human operational health risk from exposure to nerve agents. Completed GF exposure studies and extended time course and dose-response studies for VX non-threshold effects relevant to military response settings. Initiated studies for nerve agent GD that lead to a refined operational human health risk assessment. Continued and expanded evaluations of inhalation toxicology for traditional agents to deliver science-based exposure standards for operational risk management decision tools. FY 07 - Complete extended inhalation studies that define extended time, low-level exposures to nerve agents GF and VX. Deliver scientifically-based acute exposure standards to the traditional chemical warfare agents for integration into operational risk management tools. Deliver refined human health risk assessment for HD inhalation exposures suitable for incorporation into Operational Risk Management processes.	6337	5525	0	0
Threat Agent Sciences, Low Level Toxicology - Methodology Development -	0	1334	998	956
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BUDGET ACTIVITY RDT&E DEFENSE-WIDE/ BA2 - Applied Research	PE NUMBER AND TITLE 0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	PROJECT CB2
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Bullet Text (cont)	FY2006	FY2007	FY2008	FY2009
FY 07/08/09 - Initiate and complete development of technically demanding exposure and analytic methods for selected very low volatile chemical threat agents, such as non-traditional agents (NTAs) in support of DTO CB51 and DTO CB69.	0	1334	998	956
Threat Agent Sciences, Operational Toxicology - Chemical Warfare Agent Operational Exposure Hazard Assessment Research, NTA and Contact Toxicity (DTO CB69) - FY 07/08/09 - Initiate and complete research to establish the operational risk standards for military personnel potentially exposed to non-traditional chemical warfare agents as well as selected traditional threat agents. Using foundation studies initiated under Low Level Toxicology, expand and target studies that will directly lead to a human health risk assessment exposure standard for medical applications. For non-medical applications, studies will support efforts to establish detection and decontamination limits for technology development. Complete DTO CB69.	0	7060	5322	5057
Threat Agent Sciences, Operational Toxicology - Toxicokinetic and Toxicodynamic Modeling of Biological Agents - FY 06/07/08/09 - Initiate and continue development of empirically based, mathematical models to characterize population dynamics of bacterial germination and migration within the body (toxicokinetics), and address infection of target tissue under natural and altered physiological states (toxicodynamics).	400	667	333	478
Threat Agent Sciences, Agent Fate - Environmental Fate of Agents (DTO CB42) - FY 06 - Completed predictive modeling, methodology development, fundamental laboratory measurements and outdoor live agent testing of HD mustard gas and VX and GD nerve agents on operationally relevant surfaces. Used data to develop models and transitioned models to the Joint Effects Model (JEM).	5180	0	0	0

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BUDGET ACTIVITY RDT&E DEFENSE-WIDE/ BA2 - Applied Research	PE NUMBER AND TITLE 0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	PROJECT CB2
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Accomplishments/Planned Program (Cont):	FY2006	FY2007	FY2008	FY2009
<p>Threat Agent Sciences, Agent Fate - Lab/Large-Scale Wind Tunnel Studies - FY 06 - Completed surface evaporation tests of HD on operationally relevant surfaces in lab-scale and outdoor tests for model validation in support of DTO CB42.</p> <p>FY 07 - Initiate studies of thickened Chemical Warfare Agents (CWAs). Refine protocols for laboratory wind tunnels and collect data on thickened CWAs evaporation.</p> <p>FY 08 - Implement protocols for laboratory wind tunnels and collect additional data on thickened CWAs evaporation.</p> <p>FY 09 - Using protocols previously developed for laboratory wind tunnels, complete data collection for evaporation studies on thickened CWAs or substrates specified by Joint Requirements Office for Chemical, Biological, Radiological, and Nuclear Defense (JRO-CBRND) and material developments under Transformational Countermeasures Technologies Initiative (TCTI). Initiate data collection characterizing traditional agent evaporation under conditions demonstrating newly discovered phenomena.</p>	2253	3307	2098	2047

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Accomplishments/Planned Program (Cont):		FY2006	FY2007	FY2008	FY2009
Threat Agent Sciences, Agent Fate - Fundamental Laboratory Measurements - FY 06 - Completed laboratory surface evaporation tests of VX nerve agent, limited tests of GD nerve agent and HD mustard gas on operationally relevant surfaces in support of DTO CB42. FY 07 - Initiate kinetic studies of the fate of thickened CWAs on operationally relevant surfaces. FY 08 - Continue kinetic studies of the fate of thickened CWAs on operationally relevant surfaces to investigate newly identified phenomena. FY 09 - Continue kinetic studies of the fate of thickened CWAs on operationally relevant surfaces to investigate newly identified phenomena. Integrate characterization of new phenomena into models to be transitioned to the JEM.		5623	1333	839	819
Threat Agent Sciences, Agent Fate - Methodology Development - FY 06 - Completed and published reaction chemistry of HD mustard gas, and VX, and GD nerve agents on concrete, asphalt and sand in support of DTO CB42.		2161	0	0	0
Threat Agent Sciences, Agent Fate - Predictive Modeling - FY 06 - Completed HD mustard gas and VX nerve agents evaporation models from lab-scale wind tunnel data and initiated validation of model predictions in limited field trials in support of DTO CB42. Completed development of the liquid contact model and initiated validation of the model against experimental data. FY 07 - Develop evaporation models of thickened CWA using data from lab-scale wind tunnel data and field trials. Transition data to the JEM. FY 08/09 - Complete the development of evaporation models of thickened CWAs on operationally relevant materials based data from lab-scale wind tunnel data and field trials. Continue the transition of data to the JEM.		967	2400	1511	1474
Threat Agent Sciences, Agent Fate - Environmental Fate of Non-traditional Agents (DTO CB68) -		0	3500	2203	2150
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Bullet Text (cont)	FY2006	FY2007	FY2008	FY2009
<p>FY 07 - Initiate research to develop data sets of persistence and residual NTA concentration on operationally relevant surfaces (concrete, asphalt, painted surfaces, sand, soil, etc.) as specified by the JRO-CBRND. Characterize reactivity of the NTAs with surfaces, as well as surface penetration and the fate of NTAs over time. Methodology development is a primary thrust of this first year of the DTO.</p> <p>FY 08 - Continue research to develop data sets of persistence and residual NTA concentration on operationally relevant surfaces (concrete, asphalt, painted surfaces, sand, soil, etc.) as specified by the Joint Requirements Office. Characterize reactivity of the NTAs with surfaces, as well as surface penetration and the fate of NTAs over time.</p> <p>FY 09 - Continue research to develop data sets of persistence and residual NTA concentration on operationally relevant surfaces (concrete, asphalt, painted surfaces, sand, soil, etc.) as specified by the Joint Requirements Office, expand studies to include newly prioritized agents. Characterize reactivity of the NTAs with surfaces, as well as surface penetration and the fate of NTAs over time. Complete DTO and integrate with Transformational Countermeasures Technologies Initiative (TCTI) efforts.</p>	0	3500	2203	2150
<p>Threat Agent Sciences, Computational Chemistry - Quantitative Structure Activity Relationship (QSAR) -</p> <p>FY 06 - Completed independent assessment and evaluation of the QSAR field. Computational Chemistry - Identified, developed, integrated and validated a computational capability for in silico Predictive Modeling Tools to select a new suite of suitable CWA simulants for Operational Test and Evaluation. Developed a data mining tool to provide Indications and Warnings of enemy BW agent development/deployment.</p> <p>FY 07 - Transition COTS QSAR toolsets to the CBDP. Identify and refine applicable QSAR developed by academia and industry, e.g., in pesticide studies, for use in the CBDP to describe interactions between conventional CWA and surfaces/materials of operational interest.</p>	1000	1333	1393	0
<p>Project CB2/Line No: 014</p> <p align="center">Page 42 of 83 Pages</p> <p align="right">Exhibit R-2a (PE 0602384BP)</p>				

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Bullet Text (cont)		FY2006	FY2007	FY2008	FY2009
FY 08 - Continue to identify and refine applicable QSAR developed by academia and industry, e.g., in pesticide studies, for use in the CBDP to describe interactions between conventional CWA and surfaces/materials of operational interest.		1000	1333	1393	0
Threat Agent Sciences, Computational Chemistry - Quantum-Chemical Modeling (QCM) of Chemical Warfare Agent (CWA) Interactions - FY 06/07/08 - Initiate and continue Quantum-Chemical modeling effort to compute the interaction of CWA simulants and real CWAs on oxide surfaces and other surfaces/materials of operational interest. FY 09 - Continue Quantum-Chemical modeling effort to compute the interaction of CWA simulants and real CWAs on oxide surfaces and other surfaces/materials of operational interest. Benchmark and validate the capabilities to predict specific interactions of operational interest. Transition capabilities to Agent Characterization and Simulant Development to provide simulant design and selection methodology for use in Operational Test and Evaluation.		907	1200	1392	1701
Threat Agent Sciences, Computational Chemistry - Quantum-Chemical Modeling (QCM) Tool Development - FY 07/08 - Initiate and continue QCM dataset development to develop QSAR between NTAs and surfaces/materials of operational interest. Intent is to establish expertise and baseline against well-characterized substrates before moving toward human toxicology QSAR toolsets. FY 09 - Continue QCM dataset implementation to establish QSAR between NTAs and surfaces/materials of operational interest. Utilize expertise and baseline against well-characterized substrates and move toward human toxicology QSAR toolsets. Integrate computational chemistry capabilities into experimental planning and data utilization work.		0	2667	2784	3781
Threat Agent Sciences, Science Information Support - FY 06 - Provided support to OSD policy development efforts. FY 07 - Complete OSD policy development efforts. Support the Joint Community for policy development in support of CB Defense Operations. Complete data collection and generation to support policy development.		250	850	0	0
Total		29460	35751	24810	24307

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BUDGET ACTIVITY RD&E DEFENSE-WIDE/ BA2 - Applied Research	PE NUMBER AND TITLE 0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	PROJECT CB2
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	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>
SBIR/STTR	0	1257	0	0

Accomplishments/Planned Program	FY2006	FY2007	FY2008	FY2009
SBIR - FY 07 - Small Business Innovative Research.	0	1257	0	0
Total	0	1257	0	0

C. <u>Other Program Funding Summary:</u>	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>	<u>FY 2010</u>	<u>FY 2011</u>	<u>FY 2012</u>	<u>FY 2013</u>	<u>To Compl</u>	<u>Total Cost</u>
CB3 CHEMICAL BIOLOGICAL DEFENSE (ATD)	105134	113081	20662	21028	21935	14241	14310	13823	Cont	Cont
TT3 TECHBASE TECHNOLOGY TRANSITION	13661	12623	7667	8150	8463	8329	9430	9533	Cont	Cont

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BUDGET ACTIVITY RDT&E DEFENSE-WIDE/ BA2 - Applied Research	PE NUMBER AND TITLE 0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	PROJECT TB2
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COST (In Thousands)	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012	FY 2013	Cost to	Total Cost
	Actual	Estimate	Complete							
TB2 MEDICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)	89183	97730	151712	63773	51565	50672	52948	52995	Continuing	Continuing

A. Mission Description and Budget Item Justification:

Project TB2 MEDICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH): This project area funds applied research developing vaccines, therapeutic drugs, and diagnostic capabilities which provide an effective medical defense against validated biological threat agents including bacteria, toxins, and viruses. Innovative biotechnology approaches will be incorporated to advance medical systems designed to rapidly identify, diagnose, prevent, and treat disease due to exposure to biological threat agents. Categories for this project area include core science and technology program areas in medical biological defense capability areas (Pretreatments, Diagnostics, Therapeutics) and directed research areas such the Defense Technology Objectives (DTO), the Chemical and Biological Defense Initiative (CBDI) fund and the Transformational Medical Technologies Initiative or TMTI). The TMTI was launched in FY06 as a key Quadrennial Defense Review initiative to respond to the threat of emerging or intentionally bioengineered biological threats. It augments the core science and technology area by expanding the novel programs currently funded under the core Therapeutics program and introducing new technologies for developmental focus. The TMTI is a novel experiment to develop drugs that are broad spectrum in nature by using non-traditional and high risk approaches to accelerate the development and licensure of new medicines. Applied research efforts supported under this initiative are focused on the evaluation of broadspectrum therapeutic candidates with activity against intracellular pathogen and hemorrhagic fever virus infection, and rapid resequencing technologies. Teaming the core program and TMTI provides a complementary strategy (single agent versus broad spectrum, conventional versus emerging threats and established model systems versus expanded integration of novel technology, respectively) towards the development of effective medical countermeasures against biothreat agents.

B. Accomplishments/Planned Program

	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>
Congressional Interest Items	30457	7331	0	0

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Accomplishments/Planned Program				
	FY2006	FY2007	FY2008	FY2009
FY 06 - Advanced Emergency Medical Response Training.	2426	0	0	0
FY 06 - Proteomics R&D improved Drugs and Diagnostics against BW - Investigated the mechanism of action of immunomodulators, to open new paths in development of broad-spectrum adjuvant/immunomodulator drugs and diagnostic tools using differential proteomic analysis.	991	0	0	0
FY 06 - Novel Viral Biowarfare Agent ID and Treatment (NOVBAIT) - Developed a novel approach to anti-viral therapeutics based on high-throughput screening of compounds against intermediates of the virus capsid assembly pathway.	3961	0	0	0
FY 06 - Biowarfare Diagnosis and Therapy via Mismatch Repair - Produced in mass humanized bivalent and trivalent Botulinum neurotoxins.	2526	0	0	0
FY 06 - Global Pathogen Portal (PathPort) - Explored the rapid detection, identification, and forensic attribution of high-priority biothreat pathogens by using analysis and visualization tools.	2476	0	0	0
FY 06 - Institute for Advanced Pharmaceutical Sciences.	991	0	0	0
FY 06 - Rapid Pathogen Amplification and Detection System (RPADS) - Developed a bacteriophage technology that has the potential to improve detection of clinical and environmental agents while decreasing cost, time, and equipment size/weight.	991	0	0	0
FY 06 - Immuno-array - Developed a proteome microarray as a tool for flexible, rapid characterization of new and novel pathogens and expedited development of countermeasures.	991	0	0	0
FY 06 - Bug-to-Drug Program - Integrated existing and emerging biotechnologies to support an end-to-end drug development system which will accelerate the drug development cycle for new biothreat agents.	4952	0	0	0
FY 06 - Marburg Countermeasures - Determined if Phosphorodiamidate Morpholino Oligomers (PMO) can target Marburg virus host factor gene expression.	2971	0	0	0
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Accomplishments/Planned Program (Cont):		FY2006	FY2007	FY2008	FY2009
Multi-purpose Biodefense Immuno Array - FY 06 - Developed protein microarrays to measure immune responses to hemorrhagic virus, two pox viruses and bacillus anthracis proteomes. The arrays will provide new knowledge to aid the development of new vaccines, therapeutics and diagnostics. FY07 - Developed protein microarrays to measure immune responses to hemorrhagic virus, two pox viruses and bacillus anthracis proteomes. The arrays will provide new knowledge to aid the development of new vaccines, therapeutics and diagnostics.		1387	1090	0	0
Botulinum Neurotoxin Research (Only for Research on fluorescence resonance energy transfer assays and antagonists) - FY 06 - Developed a new assay which is designed to detect Botulinum (A-G) in the environment and on exposed animals, humans, and culture cells. FY 07 - Develop a new assay which is designed to detect Botulinum (A-G) in the environment and on exposed animals, humans, and culture cells.		2526	2377	0	0
Alternative Delivery Methods for Recombinant Protein Vaccines - FY 06 - Developed countermeasures against bioterrorist attack by evaluating advanced vaccine delivery platforms that can be deployed rapidly and that allow self-vaccination. FY 07 - Develop countermeasures against bioterrorist attack by evaluating advanced vaccine delivery platforms that can be deployed rapidly and that allow self-vaccination.		3268	1882	0	0
FY 07 - Asymmetrical Protocols for Biological Defense Enhancement.		0	991	0	0
FY 07 - National Center for Integrated Civilian-Military Medical Response and Homeland Defense (only for DoD military activities).		0	991	0	0
Total		30457	7331	0	0
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	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>
Transformational Medical Technology Initiative	17486	49087	113024	26169

Accomplishments/Planned Program	FY2006	FY2007	FY2008	FY2009
<p>Multiagent (Broad Spectrum) Medical Countermeasures -</p> <p>FY 06 - Initiated pursuit of computer-based technologies that enable the development of small molecule medical countermeasure candidates based upon structure/function analysis of either BW agent or host response pathway target. Initiated development of ex vivo cell-based model systems or minimize requirements for the study of medical countermeasure bioactivity, efficacy and safety. Initiated a rapid re-sequencing technology using state-of-the-art, commercially available microarrays.</p> <p>FY 07 - Initiate evaluation of novel compounds for anti-bacterial effects against intracellular bacterial pathogens in preparation for Investigational New Drug (IND) submission. Continue pre-IND studies for antisense RNA therapeutics against hemorrhagic fever virus pathogens. Evaluate novel inhibitors for effectiveness against hemorrhagic fever viruses and intracellular bacterial pathogens. Initiate evaluation of genetic methods for identifying broad spectrum host pathway therapeutic targets. Initiate studies designed to develop and characterize novel immunoadjuvant compounds. Initiate evaluation of specific compounds designed to inhibit key pathogen and/or host target molecules. Expand development of rapid re-sequencing applications and formation of bioinformatics database. Initiate candidate drug development phase.</p>	17486	49087	113024	26169

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Bullet Text (cont)	FY2006	FY2007	FY2008	FY2009
<p>FY 08 - Continue the evaluation of novel compounds for anti-bacterial effects against intracellular bacterial pathogens in support of IND submission. Evaluate and validate studies of antisense RNA therapeutic candidate drugs against hemorrhagic fever virus pathogens in preparation and support of IND studies. Continue the evaluation of novel inhibitors of hemorrhagic fever viruses and intracellular bacterial pathogens. Continue the evaluation and development of genetic methods for identifying broad spectrum host pathway therapeutic targets. Continue studies designed to develop and characterize novel immunoadjuvant compounds. Expand the evaluation of specific compounds designed to inhibit key pathogen and/or host target molecules. Continue to expand development of rapid re-sequencing applications. Initiate pre-clinical phase. Initiate studies necessary to support an IND application and a Milestone A decision.</p> <p>FY 09 - Continue to evaluate novel compounds for anti-bacterial effects against intracellular bacterial pathogens. Further evaluate and validate studies of antisense RNA therapeutic candidate drugs against hemorrhagic fever virus pathogens in preparation and support of IND studies. Maintain efforts to evaluate novel inhibitors of hemorrhagic fever viruses and intracellular bacterial pathogens. Carry on development of genetic methods for identifying broad spectrum host pathway therapeutic targets and begin the evaluation of new approaches to inhibit these therapeutic targets. Promote studies designed to develop and characterize novel immunoadjuvant compounds. Continue to expand the evaluation of specific compounds designed to inhibit key pathogen and/or host target molecules. Apply rapid re-sequencing technology to real world samples. Initiate clinical phase. Initiate a Phase 1 clinical trial and studies necessary to support a Milestone B decision.</p>	17486	49087	113024	26169
Total	17486	49087	113024	26169

	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>
Diagnostics	9708	9879	9274	7665

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Accomplishments/Planned Program	FY2006	FY2007	FY2008	FY2009
<p>Diagnostic Technologies - FY 06 - Recommended a block improvement to the Joint Biological Agent Identification and Diagnostic System (JBAIDS) Program Office to replace the current DNA extraction kit in the Block I deployment pallet with a Commercial off-the-shelf (COTS) kit; recommendation was accepted. Initiated multi-center study comparing the recommended COTS Block I DNA extraction kit to automated DNA extraction methods. Accelerated development of alternate sampling/extraction techniques to address the JBAIDS Block I gap in sample processing. Designed multiplexed nucleic acid assays for the detection and identification of validated threat agents in clinical samples. Assessed novel technologies, such as microarrays, for suitability as a next generation diagnostic device. Continued to test DoD developed assays, reagents and sample preparation techniques and platforms in field and animal studies. Evaluated newly developed assays targeting the presence of active toxin in a clinical sample. Expanded evaluation of new chemistries for the identification of BWA to latest state-of-the-art methods. Matured recombinant DNA technologies for mass immunodiagnostic reagent production. Continued to build a pathogen database for a Defense Advanced Research Projects Agency (DARPA) transitioned broad range pathogen detection system potentially capable of identifying genetically engineered bacterial strains. Further developed techniques to develop a proteomics microarray to establish an analytic profile for threat agents. Utilized proteomics data to design immunologic assays for BWA detection. Assessed components of future integrated diagnostic systems.</p>	8208	6879	7674	7665

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Bullet Text (cont)	FY2006	FY2007	FY2008	FY2009
<p>FY 07 - Complete a study examining the COTS Block I DNA extraction kit to automated DNA sample processors and provide recommendation to the JBAIDS Program Office. Using animal models exposed to biothreat agents, identify the optimal matrices/tissues for biological pathogen identification and determine testing windows of diagnostic opportunity using Service developed assays. Expand design of multiplexed assays to include immunoassays. Optimize confirmatory tests for ricin and botulinum toxins. Sponsor laboratory based research targeting the diagnostic implications of biothreat relevant toxins in the body and their relevant analytical parameters. Continue research directed at increasing sample concentration and extending sample viability prior to testing. Augment database for a DARPA transitioned broad range pathogen detection system capable of potentially identifying genetically engineered strains. Utilize proteomics data to design immunologic assays for biological pathogen detection. Maintain technological assessment of components of next generation diagnostic devices. Develop a decision matrix to effectively assess next generation diagnostic devices. Investigate technologies capable of integrating nucleic acid and immunodiagnostic testing to support the JBAIDS next generation diagnostic capability. Pursue rapid sequencing methods to enhance diagnostic capabilities of existing Polymerase Chain Reaction (PCR)-based assays. Initiate development of real time PCR assays to identify genes responsible for antibiotic resistance in biothreat agents. Continue to use recombinant DNA technologies to enhance immunologic reagent production.</p>	8208	6879	7674	7665

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Bullet Text (cont)	FY2006	FY2007	FY2008	FY2009
<p>FY 08 - Apply decision matrix to developmental testing on next generation diagnostic devices with an emphasis on technologies capable of integrating sample preparation and nucleic acid and immunodiagnostic testing. Continue a study of laboratory based research targeting the diagnostic implications of toxins in the body and their relevant analytical parameters. For additional agents, use animal models exposed to BWAs to identify the optimal matrices/tissues for biological pathogen identification and determine test windows of diagnostic opportunity. Incorporate multiplexed immunoassays onto existing platforms. Test recombinant DNA reagents on existing immunodiagnostic platforms. Complete a study directed at increasing sample concentration and extending sample viability prior to testing. Complete initial build/validation of a database for a DARPA transitioned broad range pathogen detection system capable of potentially identifying genetically engineered strains. Adapt existing PCR assays to a rapid sequencing platform. Continue to develop real time PCR assays to identify genes responsible for antibiotic resistance in biothreat agents. Validate immunologic assays designed from proteomics data.</p> <p>FY 09 - Continue to apply decision matrix to developmental testing on next generation diagnostic devices with emphasis on technologies capable of integrating sample processing, nucleic acid and immunodiagnostic testing. Based on results, assess/expand study using animal models exposed to biothreat agents in order to identify the optimal matrices/tissues for biological pathogen identification and test windows of diagnostic opportunity using Service developed assays. Promote use of recombinant DNA reagent production and incorporate onto existing systems. Develop improved test assays utilizing new technologies and approaches that enhance diagnosis of early exposure to BWAs. Complete a study of laboratory based research targeting the diagnostic implications of toxins in the body.</p>	8208	6879	7674	7665
<p>Diagnostics, Methodology to Facilitate Development of Biological Warfare Threat Agent Detection and Medical Diagnostic Systems (DTO CB56) - FY 06 - Continued to elevate previously transitioned assays to test and evaluation with preference for assays selected for JBAIDS Block I.</p>	1500	1600	0	0
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Bullet Text (cont)	FY2006	FY2007	FY2008	FY2009
FY 07 - Pursue elevation of previously transitioned assays to test and evaluation with priority for assays selected for JBAIDS Block I.	1500	1600	0	0
<p>Diagnostics, Rapid Detection, Threat Assessment and Attribution of Genetically Engineered Biothreat Organisms Using Microarray-Based Resequencing Technologies (DTO CB64) - (Transitioned from Emerging Threats) -</p> <p>FY 07 - Demonstrate greater than threefold scale-up of high-throughput experimental protocols and systems for rapid high-throughput microarray-based resequencing. Resequence 10 B. anthracis and 10 Y. pestis group genomes; release data to other relevant DoD projects. Expand biothreat agent collection. Evaluate microarray feature size reduction/increased density on two platforms. Develop resequencing and genotyping arrays for 10 Arenaviruses and 5 Filoviridae viruses.</p> <p>FY 08 - Demonstrate threefold scale-up of experimental protocols and systems. Resequence 30 B. anthracis and 30 Y. pestis group genomes, releasing data to other relevant DoD projects. Expand strain collection, focusing on agents most relevant to warfighters. Evaluate further microarray feature improvements on two microarray platforms. Develop resequencing and genotyping arrays for 15 Bunyaviridae and Togaviridae viruses.</p>	0	1400	1600	0
Total	9708	9879	9274	7665

	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>
Emerging Threats	2359	2550	0	0

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Accomplishments/Planned Program	FY2006	FY2007	FY2008	FY2009
Emerging Threats, Genetically Engineered Threats - FY 06 - Conducted evaluation of spore germination inhibitors and their effectiveness. Identified virulence factors/toxins and biochemical pathways as targets for the development of countermeasures active against a number of BW agents. FY 07 - Perform research to support the development of countermeasures for genetically engineered threats that will be supported by the Therapeutics program.	866	2550	0	0
Emerging Threats, Rapid Detection, Threat Assessment and Attribution of Genetically Engineered Biothreat Organisms Using Microarray-Based Resequencing Technologies (DTO CB64) - FY 06 - Initiated installation and design of rapid, inexpensive, high-throughput, microarray-based DNA resequencing of biothreat agent genomes, for bacterial pathogens and RNA viruses whether they are naturally occurring, newly arising, or genetically engineered strains. Developed and implemented collection procedures and expanded biothreat agent strain collection. Evaluated two high-density microarray systems as whole genome resequencing platforms in preparation for whole genome scale-up. Developed data analysis pipeline. Beginning in FY07, DTO CB64 will fall under the Diagnostics Capability area.	1493	0	0	0
Total	2359	2550	0	0

	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>
Pretreatments	11125	13261	10428	11963

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Accomplishments/Planned Program	FY2006	FY2007	FY2008	FY2009
<p>Pretreatments, Multiagent Vaccines, Western and Eastern Equine Encephalitis (WEE/EEE) Vaccine Constructs for a Combined Equine Encephalitis Vaccine (DTO CB58) -</p> <p>FY 06 - Investigated new EEE vaccine approaches in animal models in combination with WEE and Venezuela Equine Encephalitis (VEE) vaccine construct(s) or alternate VEE vaccine candidates made in the DNA- or replicon-based vaccine platforms. Developed definitive non-human primate model to evaluate the efficacy of separate and combined VEE/WEE/EEE vaccine candidates. Analyzed additional WEE/EEE mutants with various engineered attenuating mutations. Initiated duration of immunity studies with lead candidates for each platform, comparing the individual constructs and trivalent formulations.</p> <p>FY 07 - Initiate the evaluation of live, site-directed mutagenized, attenuated viral vaccines. Perform dose ranging studies in non-human primates (NHPs) for efficacy of multiagent viral vaccine candidates. Assess a combined VEE, EEE, and WEE, vaccine by identifying and characterizing WEE and EEE vaccine constructs that would be appropriate to combine into a single vaccine with a VEE live-attenuated vaccine candidate, or with alternative VEE vaccine candidates made in the DNA- or replicon-based vaccine platforms. Conduct antigen interference studies for the combined VEE/WEE/EEE vaccine in the definitive animal model. Accelerate the construction and evaluation of VEE/WEE/EEE vaccine candidate constructs in various delivery platforms in preparation for down-selection of vaccine candidate platforms.</p> <p>FY 08 - Complete the evaluation of live, site-directed mutagenized, attenuated viral vaccines. Conclude dose ranging studies in NHPs for efficacy of multiagent viral vaccine candidates. Optimize a combined VEE, EEE, and WEE vaccine by identifying and characterizing WEE and EEE vaccine constructs that would be appropriate to combine into a single vaccine with a VEE live-attenuated vaccine candidate, or with alternative VEE vaccine candidates made in the DNA- or replicon-based vaccine platforms. Conclude antigen interference studies for the combined VEE/WEE/EEE vaccine in the definitive animal model. Perform down-selection of vaccine candidate platforms. DTO CB58 ends in FY 2008.</p>	605	1247	500	0
Pretreatments, Multiagent Vaccines, Multi-agent (molecular) Vaccines for Bio-Warfare Agents (DTO CB65) -	2500	3400	3000	4000
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Bullet Text (cont)	FY2006	FY2007	FY2008	FY2009
<p>FY 06 - Identified pathogens to be targeted as the third component of a trivalent vaccine and initiated candidate antigen incorporation into vaccine constructs for evaluation. Explored both molecular and protein-based multivalent vaccine platforms. Developed the optimal DNA backbone in combination with adjuvant formulation. Evaluated multi-epitope DNA vaccine constructs. Explored the use of alternative delivery strategies for optimizing the efficacy of genetic immunization. Investigated DNA vector delivery systems that stimulate protective immunity following minimal dosing.</p> <p>FY 07 - Express select bio-threat agent target antigens and assess immunogenicity and protective efficacy in animal models alone and in combination with anthrax and plague elements. Develop the use of Virus-Like Particles (VLPs) for multiagent vaccine development. Characterize the underlying protective response and evaluate for possible interference phenomena. Continue to explore alternative genetic vaccine delivery strategies and adjuvant formulations. Conduct a comparative analysis of genomic and recombinant vaccine candidates for efficacy. Assess multiepitope DNA vaccine constructs. Initiate studies using a multivalent spore display platform.</p> <p>FY 08 - Assess immunogenicity and efficacy of multivalent vaccines which include anthrax and plague elements. Define protective responses and evaluate possible interference phenomena in multiagent formulations. Expand the use of VLPs as well as other potential platforms for multiagent vaccine development. Continue to explore alternative genetic vaccine delivery strategies and adjuvant formulations for the development of immunity against intracellular bacterial pathogens. Conduct efficacy testing of genomic and recombinant vaccine candidates. Optimize multiepitope DNA vaccine constructs. Continue the evaluation a multivalent spore display vaccine platform.</p>	2500	3400	3000	4000

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Bullet Text (cont)					
		FY2006	FY2007	FY2008	FY2009
FY 09 - Optimize multiagent vaccines which include anthrax and plague components in animal models. Test multiagent VLPs for efficacy in animal models. Characterize the underlying protective response and evaluate for possible interference phenomena. Optimize alternative genetic vaccine delivery strategies and novel adjuvant formulations for the development of vaccines against intracellular bacterial pathogens. Finalize efficacy testing of genomic and recombinant vaccine candidates. Complete testing of genomic and recombinant vaccine candidates, particularly multiepitope DNA vaccine constructs. Test spore-based vaccines in animal models.		2500	3400	3000	4000
Pretreatments, Multiagent Vaccines - (Formerly under Animal Models and Resuscitative Intervention) - FY 06 - Explored genomics/proteomics-based high throughput approaches to identify potential vaccine target antigens. Evaluated the use of VLPs to induce an immune response against targeted antigens and characterize the nature of the response. Initiated evaluation of DNA-based immunization platforms. Explored the use of novel approaches to antigen presentation including recombinant protein and/or fusion protein constructs. Investigated the uses of CpG oligonucleotides as vaccine adjuvants. FY 07 - Expand studies of genomics/proteomics-based high throughput approaches to identify potential vaccine target antigens for selected biothreat agents. Assessment of candidate anthrax/plague/ricin multi-agent vaccines in animal models. Continue development and refinement of in vitro correlates of immunity against intracellular bacterial pathogens. Determine efficacy/immunogenicity and optimization studies of new antigen vaccine formulations considering alternative adjuvants, routes of administration, and dosage schedules. Evaluate novel delivery systems for enhanced vaccine delivery and efficacy in support of the rapid development of multiagent vaccines. Investigate whether CpG oligonucleotides provide enhancement as vaccine adjuvants. Explore aspects of the innate immune response for possible adjuvant effects applicable to vaccine development.		700	2390	1877	1436
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Bullet Text (cont)	FY2006	FY2007	FY2008	FY2009
<p>FY 08 - Conduct further animal studies for development of candidate anthrax/plague/ricin multi-agent vaccine. Maintain studies of in vitro correlates of immunity for select candidate vaccine projects. Pursue optimization studies of new antigen vaccine formulations considering alternative adjuvants, routes of administration, and dosage schedules. Evaluate systems for the rapid development of multiagent vaccines, including novel vaccine platforms and novel delivery systems for enhanced vaccine delivery of selected vaccine candidates. Review candidate vaccines for down-selection to primary candidates.</p> <p>FY 09 - Continue the assessment of candidate anthrax/plague/ricin multi-agent vaccine in animal models. Pursue advanced genetic vaccine delivery strategies for selected vaccines and evaluate efficacy in animal models.</p>	700	2390	1877	1436
<p>Pretreatments, Vaccine Research Support -</p> <p>FY 06 - Evaluated intracellular pathogen candidate antigens using animal model systems including the use of alternative delivery platforms. Initiated B and T cell epitope mapping of lead protective antigen candidates. Assessed in vitro correlates of immunity for specific threat agents. Investigated novel antigen targets for next generation anthrax and plague vaccine development. Evaluated the immunogenicity of intact catalytic and translocation domains of botulinum neurotoxins (BoNT). Continued developing in-process and release assays for recombinant BoNT Hc vaccine candidates. Cloned and expressed proposed Staphylococcal Enterotoxin A (SEA)/Staphylococcal Enterotoxin B (SEB) structural determinants; determined stability of immunogens; raised neutralizing antibodies against immunogens and test for cross-reactivity among SE serotypes using in vitro systems. Compared various adjuvants and routes of administration for the V3526 (VEE) vaccine candidate. Explored additional uses of VLPs as antigen delivery platforms for filovirus vaccine development.</p>	5286	3794	2444	3536
<p>Project TB2/Line No: 014</p> <p align="center">Page 58 of 83 Pages</p> <p align="right">Exhibit R-2a (PE 0602384BP)</p>				

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Bullet Text (cont)	FY2006	FY2007	FY2008	FY2009
<p>FY 07 - Explore additional intracellular pathogen target antigens using animal model systems including the use of alternative delivery platforms. Continue B and T cell epitope mapping of lead protective antigen candidates. Expand studies on the immunogenicity of intact functional domains of botulinum neurotoxins (BoNT). Evaluate immunogenicity of enhanced next generation anthrax and/or plague vaccine candidates. Continue to characterize in vitro correlates of immunity for specific threat agents. Identify novel antigen targets for next generation anthrax and plague vaccine development in animal models. Begin evaluating the protective efficacy of intact catalytic and translocation domains of botulinum neurotoxins (BoNT). Evaluate filovirus cellular immunity parameters. Develop animal models for Ebola Sudan strain.</p> <p>FY 08 - Down-selection to candidate vaccines for advanced development. Validate additional intracellular bacterial pathogen target antigens using animal model systems. Continue B and T cell epitope mapping of lead protective antigen candidates. Continue studies on the immunogenicity and efficacy of intact functional domains of BoNT. Evaluate the efficacy of enhanced next generation anthrax and/or plague vaccine candidates in animal models. Continue to evaluate in vitro correlates of immunity for specific threat agents. Pursue development of filovirus immunoassays and examine contributions of the cellular immune responses. Conclude animal model development for the Ebola Sudan strain.</p> <p>FY 09 - Develop validation assays for selected candidate vaccines for advanced development. Conduct toxicity analyses of selected vaccine candidates in preparation for IND submission. Optimize intracellular pathogen target antigens and prepare to test in non-human primate models. Continue the exploration of additional intracellular pathogen target antigens using animal model systems including the use of alternative delivery platforms. Complete B and T cell epitope mapping of lead protective antigen candidates. Complete evaluation of the protective efficacy of intact functional domains of BoNT in small animal models; prepare for non-human primate studies. Prepare to evaluate enhanced next generation anthrax and/or plague vaccine candidates in non-human primates. Optimize filovirus immunoassays and evaluate their ability to predict protection.</p>	5286	3794	2444	3536
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Accomplishments/Planned Program (Cont):	FY2006	FY2007	FY2008	FY2009
<p>Pretreatments, Vaccine Technology Development - (formerly under Resuscitative Intervention) -</p> <p>FY 06 - Tested novel adjuvants designed to enhance the efficacy of genetic vaccines in non-human primates (e.g. toll-like receptor agonists, cationic antimicrobial peptides, immunostimulatory oligonucleotides). Accelerated the development and design of generic gene-based vaccines targeting common target sequences in pathogens. Explored gene-based poxvirus vaccines. Developed targets for a generic Bacillus molecular vaccine. Expanded effort in vaccine development to include the evaluation of novel immunization platforms and therapeutic immunization strategies for post-exposure treatment. Assessed user-friendly vaccination modalities which confer rapid protection following minimal dosing.</p> <p>FY 07 - Initiate evaluation of a Bacillus generic molecular vaccine in animal models. Continue development of gene-based poxvirus vaccines and determine immunogenicity and efficacy in animal models. Determine adjuvant formulations/systems, including oligonucleotide-based, that enhance the efficacy of molecular vaccines in animal models. Expand alternative immunization platforms such as VEE replicons for efficacy against selected biothreat pathogens and/or toxins. Continue the exploration of candidate vaccine efficacy in conjunction with Toll-like receptors (TLR)-agonist delivery and/or recombinant interleukins. Determine cross-reactive epitopes/antigens which may confer immunity against selected bio-threat agents. Continue assessment of user-friendly vaccination modalities which confer rapid protection following minimal dosing. Pursue efforts in vaccine development to include the evaluation of novel immunization platforms and therapeutic immunization strategies for post-exposure treatment.</p>	2034	2430	2607	2991

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Bullet Text (cont)	FY2006	FY2007	FY2008	FY2009
<p>FY 08 - Assess the immunogenicity of a Bacillus generic molecular vaccine in animal models. Optimize gene-based poxvirus vaccines and determine immunogenicity and efficacy in Non-human primate models. Continue to explore adjuvant formulations/systems, including oligonucleotide-based, that enhance the efficacy of molecular vaccines in animal models. Validate alternative immunization platforms such as VEE replicons for efficacy against selected biothreat pathogens and/or toxins. Test the ability of TLR-agonist delivery and/or recombinant interleukins to enhance vaccine efficacy in animal models. Initiate evaluation of cross-reactive antigens which may confer immunity against selected bio-threat agents in animal models. Pursue identification and testing of user-friendly vaccination modalities which confer rapid protection following minimal dosing.</p> <p>FY 09 - Assess the efficacy of a Bacillus generic molecular vaccine in non-human primate animal models. Prepare gene-based poxvirus vaccine candidate for possible Investigational New Drug (IND) studies. Optimize oligonucleotide-based adjuvant formulations or other systems that enhance the efficacy of molecular vaccines in animal models. Test alternative immunization platforms, such as VEE replicons, for efficacy against selected biothreat agents in appropriate animal models. Optimize the use of TLR-agonist delivery and/or recombinant interleukins to enhance vaccine efficacy in animal models. Continue to identify cross-reactive epitopes/antigens which confer immunity against multiple bio-threat agents. Assess user-friendly, self-administered vaccination modalities which confer rapid protection following minimal dosing.</p>	2034	2430	2607	2991
Total	11125	13261	10428	11963

	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>
Therapeutics	18048	14678	18986	17976

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BUDGET ACTIVITY RDT&E DEFENSE-WIDE/ BA2 - Applied Research	PE NUMBER AND TITLE 0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)		PROJECT TB2	
Accomplishments/Planned Program	FY2006	FY2007	FY2008	FY2009
<p>Therapeutics, Therapy for Smallpox and Other Pathogenic Orthopox Viruses (DTO CB54) - FY 06 - Conducted initial evaluation in pock lesion variola primate model at the Centers for Disease Control and Prevention. Evaluated oral cidofovir prodrug against monkeypox in primate model to determine drug efficacy. Evaluated minimal and sufficient viral therapeutic requirements such as dose, route, pharmacokinetics, and pharmacodynamics. Performed appropriate testing in non-human primates for FDA licensure consideration under the FDA Animal Efficacy Rule. Oral cidofovir achieved investigational new drug (IND) status for the smallpox indication.</p> <p>FY 07 - Conduct advanced efficacy studies of the oral prodrug of cidofovir as a therapy for smallpox, to support preparation of a new drug application (NDA) package for the FDA. Perform FDA required studies to support transition of ST-246, as an oral therapeutic for orthopox virus infection, to advanced development. Additional studies to support the transition of oral therapeutics to advanced development will be supported by the Viral Therapeutics program (TB3) in 2008. Complete DTO CB54.</p>	1815	1800	0	0
<p>Therapeutics, Viral, Therapeutic Strategies for Treating Filovirus (Marburg and Ebola Viruses) Infection (DTO CB63) - FY 06 - Concluded studies to select anti-Marburg monoclonal antibodies for molecular reengineering and primate testing. Initiated shift from discovery of protein targets for Marburg virus therapy to testing of compounds to inhibit protein-protein interactions. Expanded characterization of the role of neutrophils in innate and adaptive immunity to Marburg virus, focusing on cellular pathways possibly common to many viruses. Evaluated the utility of recombinant nematode anticoagulant protein c2 (rNAPc2) against Marburg hemorrhagic fever in non-human primates. Completed DTO CB63.</p>	500	0	0	0
<p>Project TB2/Line No: 014</p>				

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BUDGET ACTIVITY RDT&E DEFENSE-WIDE/ BA2 - Applied Research	PE NUMBER AND TITLE 0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	PROJECT TB2
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Accomplishments/Planned Program (Cont):	FY2006	FY2007	FY2008	FY2009
<p>Therapeutics, Therapy for Ebola and Marburg Virus Infections (DTO CB67) -</p> <p>FY 07 - Initiate evaluation of therapeutic technologies developed in DTO CB63 against the Ebola virus and Marburg virus in vitro and in animal models. Technologies include antisense oligonucleotides, recombinant human monoclonal antibodies, small interfering RNAs (siRNAs), small molecules, and therapeutic vaccines. Improve existing animal models for filoviral hemorrhagic fever. Initiate preliminary comparative efficacy studies to identify best performing strategies.</p> <p>FY 08 - Optimize dose and regimen for therapeutic technologies in relevant animal models of Ebola virus and Marburg virus. Evaluate lead candidates for specific viral therapeutic requirements including pharmacokinetics and pharmacodynamics.</p> <p>FY 09 - Complete proof-of-concept studies for lead candidate technologies as they transition to development.</p>	0	2331	1372	811

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BUDGET ACTIVITY RDT&E DEFENSE-WIDE/ BA2 - Applied Research		PE NUMBER AND TITLE 0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)		PROJECT TB2	
Accomplishments/Planned Program (Cont):		FY2006	FY2007	FY2008	FY2009
<p>Therapeutics, Viral -</p> <p>FY 06 - Screened novel and currently available antiviral technologies, including interferons, Virus Like Particles (VLP), small interfering RNA (siRNA), small compounds, artificial nucleases and monoclonal antibodies, against viral threat agents in vitro. Evaluated lead candidates using in vivo efficacy models. Developed additional applied technologies that integrate established and emerging viral therapeutic modalities into suitable candidate therapies.</p> <p>FY 07 - Maintain multi-pronged approach to discovery and development of antiviral technologies against traditional and emerging viral threat agents in vitro and in vivo. Incorporate in silico screening into the drug discovery process. Assess lead candidates for specific viral therapeutic requirements such as dose, route, pharmacokinetics, pharmacodynamics. Investigate the use of metal nanoparticles as antiviral therapeutics. Explore adjuvant immunomodulatory and host-response therapeutic interventions in in vitro and in vivo systems.</p> <p>FY 08 - Optimize key dosing, administration, and pharmacological characteristics of leading antivirals in non-human primate models. Utilize in silico, in vitro and in vivo models to consider novel and currently available antiviral technologies as therapeutics against traditional and emerging viral threat agents. Screen metal based nanomaterials for their ability to inhibit isolated viral enzymes. Develop immunomodulatory and host-response interventions as adjuvants to existing and emerging antiviral therapeutics.</p> <p>FY 09 - Determine dose dependent inhibition of viral expression by nanomaterial based therapeutics in an in vitro model system. As therapeutics effective against existing threats progress to advanced development, conduct proof-of-concept studies aimed at identifying therapeutic candidates for emerging and genetically engineered threats.</p>		3129	3230	588	430
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BUDGET ACTIVITY RDT&E DEFENSE-WIDE/ BA2 - Applied Research	PE NUMBER AND TITLE 0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)		PROJECT TB2	
Accomplishments/Planned Program (Cont):	FY2006	FY2007	FY2008	FY2009
<p>Therapeutics, Bacterial -</p> <p>FY 06 - Screened novel and currently available antibiotic technologies against anthrax, plague, and burkholderia infections. Technologies include small molecules, antimicrobial peptides, monoclonal antibodies, RNA inhibitors, and cytokine-based therapeutic candidates. Evaluated CpG motifs and heat shock protein 70 (HSP70) (stimulators of the immune response) as immunomodulators to be used in conjunction with bacterial therapeutics.</p> <p>FY 07 - Refine conceptual development and execute in vivo testing of novel broad-based innate immunomodulator therapeutic approaches against naturally occurring and genetically engineered category A and B bacterial pathogens. Consider specific licensed and investigational antibacterial technologies for use against these agents. Initiate development of a nanobody based immunotherapeutic against plague. Develop a screening assay to identify small molecule therapeutic candidates that mimic bacteriophage activity.</p> <p>FY 08 - Examine the utility of newly FDA approved, and newly discovered antibiotics as therapeutics against bacterial threat agents. Conduct proof-of-concept evaluation of a nanobody based immunotherapeutic against plague. Evaluate small molecules with bacteriophage-like activity against plague in vitro. Expand the effort to develop novel bacterial therapeutics with activity against specific threat agents, especially tularemia, plague, and burkholderia.</p> <p>FY 09 - Complete initial evaluation of a nanobody based immunotherapeutic against plague, and extend application to other gram negative bacteria if successful. Screen small molecules with bacteriophage-like activity against plague in vitro, and extend application of assay to other gram negative bacteria. Balance efforts to evaluate potential bacterial therapeutics with both broad-spectrum activity, and activity against specific threat agents.</p>	3574	2901	6404	6142
Toxin, Therapeutic Strategies for Botulinum Neurotoxins (DTO CB59) -	1064	0	0	0
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BUDGET ACTIVITY RDT&E DEFENSE-WIDE/ BA2 - Applied Research	PE NUMBER AND TITLE 0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)		PROJECT TB2	
Bullet Text (cont)	FY2006	FY2007	FY2008	FY2009
FY 06 - Developed lead mixtures of human antibodies against Botulinum Neurotoxin (BoNT) as passive immunotherapeutics in vivo. Completed in vitro testing of combinations of monoclonal antibodies against multiple BoNT serotypes and proof-of-concept studies with lead BoNT active-site inhibitors and/or receptor antagonists in vivo using qualified surrogate endpoints of human clinical efficacy. Developed a strategy for development of BoNT therapeutic candidates. Completed DTO CB59.	1064	0	0	0
<p>Therapeutics, Toxin -</p> <p>FY 06 - Evaluated novel and currently available anti-toxin technologies against ricin toxin, Staphylococcal Enterotoxin B (SEB) and BoNT in vitro and in vivo. Technologies include small molecules, peptides, natural products and monoclonal antibodies. Tested efficacy of combinations of monoclonal antibodies against multiple BoNT serotypes in cell-based systems. Continued ongoing proof-of-concept studies with lead toxin therapeutics in vivo using qualified surrogate endpoints of human clinical efficacy. Defined the key linking technologies (peptide binding design, candidate delivery systems) that have relevance to eventual human clinical efficacy trials for toxins.</p> <p>FY 07 - Select lead monoclonal antibodies with therapeutic potential by employing in vitro and in vivo assay systems. Increase efforts to identify new SEB inhibitors. Examine the therapeutic potential of drug candidates with activity against ricin, SEB and BoNT in vitro and in vivo.</p> <p>FY 08 - Design and develop monoclonal antibodies with improved binding activity utilizing data generated from structural analysis of the BoNT receptor site. Identify potential inhibitors from compound repositories and peptide libraries using computer-modeling and co-crystal analysis. Evaluate small molecule, monoclonal antibody and single-chain antibody peptides against SEB.</p>	3923	4416	10622	10593
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Bullet Text (cont)	FY2006	FY2007	FY2008	FY2009
FY 09 - Evaluate next generation monoclonal antibodies for in vitro and in vivo efficacy against BoNT. Characterize lead compounds for potency and specificity via protease inhibition studies, cell-based assays, and in vivo bioassays. Initiate development of non-toxic mutants of BoNT as therapeutics with the potential to restore synaptic activity following neuroparalysis due to intoxication.	3923	4416	10622	10593
Therapeutics, Resuscitative Intervention - FY 06 - Developed combined injury animal model (trauma and Biological Warfare (BW)/Chemical Warfare (CW) agent) for testing therapeutics against a vapor nerve agent, a low-volatility nerve agent, and a particulate chemical agent threat. Developed combined injury animal model (trauma and BW/CW agent) for a vesicating agent. Identified early markers via genomic or proteomic analysis, and physiologic status of interactive effects of combined injury in appropriate animal model. Conducted initial evaluation of the pock lesion/variola primate model at the Centers for Disease Control. Expanded characterization of the monkeypox vs. primate-small pox model to prepare data packages for oral prodrug licensure.	4043	0	0	0
Total	18048	14678	18986	17976

	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>
SBIR/STTR	0	944	0	0

Accomplishments/Planned Program	FY2006	FY2007	FY2008	FY2009
SBIR - FY 07 - Small Business Innovative Research.	0	944	0	0
Total	0	944	0	0

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BUDGET ACTIVITY RD&E DEFENSE-WIDE/ BA2 - Applied Research	PE NUMBER AND TITLE 0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	PROJECT TB2
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C. <u>Other Program Funding Summary:</u>	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>	<u>FY 2010</u>	<u>FY 2011</u>	<u>FY 2012</u>	<u>FY 2013</u>	<u>To Compl</u>	<u>Total Cost</u>
TB3 MEDICAL BIOLOGICAL DEFENSE (ATD)	87910	89678	146539	299581	229306	129419	122230	113827	Cont	Cont

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BUDGET ACTIVITY RDT&E DEFENSE-WIDE/ BA2 - Applied Research	PE NUMBER AND TITLE 0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	PROJECT TC2
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COST (In Thousands)	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012	FY 2013	Cost to	Total Cost
	Actual	Estimate	Complete							
TC2 MEDICAL CHEMICAL DEFENSE (APPLIED RESEARCH)	27172	30796	36881	37072	35033	33328	38282	38614	Continuing	Continuing

A. Mission Description and Budget Item Justification:

Project TC2 MEDICAL CHEMICAL DEFENSE (APPLIED RESEARCH): This project funds medical chemical defense applied research and emphasizes the treatment and prevention of chemical casualties as well as the investigation of new medical countermeasures to include prophylaxes, pretreatments, antidotes, skin decontaminants and therapeutic drugs to protect U.S. forces against known and emerging chemical warfare threat agents. Capabilities are maintained for reformulation, formulation and scale-up of candidate compounds using current Good Laboratory Practices (cGLP).

B. Accomplishments/Planned Program

	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>
Congressional Interest Items	2526	991	0	0

Accomplishments/Planned Program	FY2006	FY2007	FY2008	FY2009
Mustard Gas Antidote Research Consortium (STIMAL) - FY 06 - Developed an antidote to mustard gas (HD) exposure. FY 07 - Develop an antidote to mustard gas (HD) exposure.	2526	991	0	0
Total	2526	991	0	0

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BUDGET ACTIVITY RDT&E DEFENSE-WIDE/ BA2 - Applied Research	PE NUMBER AND TITLE 0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	PROJECT TC2
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	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>
Diagnostics	1333	1467	1270	1411

Accomplishments/Planned Program	FY2006	FY2007	FY2008	FY2009
<p>Diagnostic Technologies - FY 06 - Continued applied research experiments aimed at improving detection methods in clinical samples for metabolites, adducts and/or relevant biomarkers resulting from chemical warfare agent (CWA) exposure. Finalized assessment of a noninvasive immunodiagnostic test using skin tape stripping to detect sulfur mustard skin exposure before the onset of vesication. Further developed alternate sample collection/extraction technology(s) such as solid phase micro-extraction as a rapid screening method to verify exposure to CWA; performed studies assessing the suitability of different fibers to extract nerve agent metabolites from synthetic urine and their time related stability and sensitivity. Using the DoD developed whole blood cholinesterase assay for organophosphate exposure, assessed a healthy population with no known exposure for known test marker inhibitors and atypical marker phenotypes. Established baseline studies, prepared standard curves, established linearity and limits of detection and performed quantification studies for assay development for additional selected chemical agents.</p>	499	467	1270	1411

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Bullet Text (cont)	FY2006	FY2007	FY2008	FY2009
<p>FY 07 - Accelerate applied research experiments aimed at improving detection methods in clinical samples for metabolites, adducts and/or relevant biomarkers resulting from CWA exposure. Continue to develop alternate sample collection/extraction technology(s) such as solid phase micro-extraction as a rapid screening method to verify exposure to CWA; complete fiber selection for nerve agents and evaluation of head space versus direct immersion for nerve agents. Pursue adaptation of the DoD developed whole blood cholinesterase assay for organophosphate exposure to automation/high throughput; examine changes in marker profiles after exposure to low level amounts of nerve agents and organophosphate pesticides and conduct feasibility studies for incorporating this method in a hand-held platform. Characterize relationship between dose, route-of-exposure, time-concentration of measured biomarker for the fluoride detection assay to detect VX nerve agent.</p> <p>FY 08 - Continue development alternate sample collection/extraction technology(s) such as solid phase micro-extraction as a rapid screening method to verify exposure to CWA; complete reproducibility studies for hydrolysis compounds and optimize fibers for select agents. Initiate development of a beta-lyase urinary metabolite assay. Develop a sample extraction technique and test method to detect the presence of chemical warfare analytes from hair samples. Investigate the feasibility of adapting immunodiagnostic and molecular technologies to hand-held CWA diagnostic platforms in biological samples by reviewing Small Business Innovation Research (SBIR) projects utilizing new technologies such as DNA aptamers, molecularly imprinted polymers (MIPS), lateral flow immunoassay and high affinity antibodies in conjunction with electrochemical and or fluorometric amplification/detection. Assess the feasibility of transitioning established lab-based procedures such as fluoride reactivation to field portable technology.</p> <p>FY 09 - Complete/make recommendations for alternate sample collection/extraction technology(s) such as solid phase micro-extraction as a rapid screening method to verify exposure to CWA. In animal models, evaluate the combined sample extraction and analysis procedure pre-and post CWA exposure to assess the feasibility of detecting chemical warfare analytes in hair samples. Incorporate promising SBIR technology into the core program for further development.</p>	499	467	1270	1411

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Accomplishments/Planned Program (Cont):	FY2006	FY2007	FY2008	FY2009
Diagnostics, Animal Models - FY 06 - Conducted animal studies for detecting biomarkers of CWA exposure in biological samples; explored longevity of biomarkers for the sulfur mustard blood protein adduct assay and fluoride reactivation assay by utilizing/interfacing with ongoing relevant animal exposure models. Assessed ability of immunohistological and specialized protein detection techniques to detect sulfur mustard-induced skin changes in relevant animal models. FY 07 - Continue to conduct animal studies for detecting biomarkers of CWA exposure in biological samples; complete studies exploring the longevity of biomarkers. Conduct metabolic profile (metabonomic) studies by examining blood from guinea pigs exposed to agent and assess the potential of this method as a diagnostic technique.	834	1000	0	0
Total	1333	1467	1270	1411

	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>
Emerging Threats	2681	0	0	0

Accomplishments/Planned Program	FY2006	FY2007	FY2008	FY2009
Emerging Threats, Non-Traditional Agent (NTA) Medical Countermeasures - FY 06 - Compared non-traditional and conventional nerve agents for induction of neurochemical changes. Evaluated countermeasures against non traditional cytokine agents (e.g., effect on inflammation reaction and bronchoconstriction). Identified target molecules for intervention against peptide NTAs and additional convulsant agents. Continued the development of an animal model for peptide NTAs. Transitions to Therapeutics in FY07.	2681	0	0	0
Total	2681	0	0	0

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	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>
Pretreatments	4904	8046	8270	8451

Accomplishments/Planned Program	FY2006	FY2007	FY2008	FY2009
<p>Pretreatments, Nerve Agent, Bioscavengers -</p> <p>FY 06 - Initiated the development of genetic knock-out murine animal models for catalytic bioscavenger studies. Evaluated different delivery systems for administration of recombinant and/or catalytic bioscavengers in vivo. Assessed human protein recombinant and catalytic bioscavengers, including the role of various amino acids near the active site in binding and turnover based on 3-D structure determination, molecular models, and site-specific amino acid mutations.</p> <p>FY 07 - Investigate recombinant methods and expression systems for larger scale production and purification of recombinant and catalytic bioscavenger proteins. Perform initial evaluation studies of catalytic bioscavenger molecules in genetic knock-out mice. Develop knock-out murine models for evaluation of recombinant and catalytic bioscavenger molecules. Conclude studies of the 3-D structure of human bioscavenger proteins. Continue development of peptide drugs as potential bioscavenger molecules. Identify new native/recombinant catalytic bioscavengers molecules. Define methods to improve/modify the catalytic efficiency of selected bioscavenger molecules. Evaluate more efficient delivery formulations. Refine methods(s) to significantly reduce or eliminate the inherent immunogenicity of recombinant bioscavenger molecules.</p>	4904	8046	8270	8451

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Bullet Text (cont)	FY2006	FY2007	FY2008	FY2009
<p>FY 08 - Evaluate recombinant methods and expression systems for larger scale production and purification of recombinant and catalytic bioscavenger proteins. Conduct studies of catalytic bioscavenger molecules in genetic knock-out mice. Continue to develop peptide drugs as potential bioscavenger molecules in animal models for safety and efficacy. Explore novel native/recombinant catalytic bioscavenger molecules. Utilize novel methods to improve/modify the catalytic efficiency of selected bioscavenger molecules. Assess new, more efficient delivery formulations.</p> <p>FY 09 - Refine recombinant methods and expression systems for larger scale production and purification of recombinant and catalytic bioscavenger proteins. Investigate catalytic bioscavenger molecules in genetic knock-out mice. Optimize dose and route of administration of peptide drugs as potential bioscavenger molecules. Assess efficacy of novel catalytic bioscavenger molecules. Evaluate bioscavenger molecules with increased catalytic efficiency. Test new, more efficient delivery formulations in animal models.</p>	4904	8046	8270	8451
Total	4904	8046	8270	8451

	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>
Therapeutics	15728	19994	27341	27210

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Accomplishments/Planned Program	FY2006	FY2007	FY2008	FY2009
<p>Therapeutics, Respiratory and Systemic -</p> <p>FY 06 - Refined and integrated animal models with screening protocols for therapeutic studies, including the novel use of macrolide antibiotics to protect against lung injury.</p> <p>FY 07 - Identify relevant endpoints for in vivo models. Screen compounds as therapeutic countermeasures against single and multiple agent exposures.</p> <p>FY 08 - Complete protocol and in vivo model optimization. Utilize human tissue model of inhalational exposure to screen therapeutics to protect against lung injury. Evaluate and down-select candidate compounds focusing on countermeasures effective against multiple agent exposures.</p> <p>FY 09 - Continue focus on broad based therapeutics effective against multiple agents and routes of exposures.</p>	1357	3411	4039	3937

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Accomplishments/Planned Program (Cont):					
		FY2006	FY2007	FY2008	FY2009
Therapeutics, Cutaneous and Ocular - FY 06 - Completed development of advanced animal injury models, including (1) a sulfur mustard wound healing model using non-human primates for advanced efficacy studies, (2) a hybrid sulfur mustard-thermal burn model using weanling pigs, and (3) rodent wound healing models to screen pharmacological interventions for the effective treatment of cutaneous sulfur mustard injuries. Utilize these models to evaluate commercially available wound healing products, and investigational products (e.g. antioxidant containing liposomes) for their efficacy in promoting improved healing of superficial dermal sulfur mustard injuries. Assessed instrumentation to evaluate the depth of cutaneous vesicant injury, for use as a prognostic indicator. Evaluated the effectiveness of new commercial skin decontamination formulations to agent challenge as a function of time. Considered novel decontaminating wound products that can be applied before or after exposure. Studied multi-photon imaging as a therapeutic modality. FY 07 - Complete efforts to develop in vitro tissue assays and design screening protocols to down-select candidate compounds. Initiate protocols and screen novel compounds, as well as FDA approved drugs, as therapeutics to counteract the effects of cutaneous and ocular exposure to chemical agents using in vitro and in vivo techniques. Characterize the depth of cutaneous vesicant injury. Compare the effectiveness of novel technologies to replace the M291 skin decontamination kit (SDK), focusing on products to decontaminate wounds and around the eyes. Characterize the treatment effect of compounds on neovascularization in ocular tissue, using small animal models and focusing on both gross and molecular injury and healing as a function of time. FY 08 - Maintain screening efforts to evaluate new and FDA approved compounds, and down-select those shown to be efficacious using in vitro and in vivo techniques. Determine the best candidate technologies for preventing and reversing damage to the eye following vesicant agent exposure.		4244	2711	1905	1940
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Bullet Text (cont)	FY2006	FY2007	FY2008	FY2009
FY 09 - Evaluate safety, efficacy, dosing and relevant pharmacokinetic and pharmacodynamic profiles of candidate countermeasures, and practicality of use in the modern combat environment.	4244	2711	1905	1940
<p>Therapeutics, Neurologic -</p> <p>FY 06 - Developed and refined screening protocols to down-select therapeutic candidates within a number of drug classes, including anticonvulsants anti-epileptics, neurosteroids, serotonin receptor agonists, serine racemase inhibitors, and antioxidants. Evaluated the efficacy of novel anticonvulsant compounds against nerve agent-induced seizures using in vivo models. Determined the efficacy of midazolam, and/or anticholinergic compounds against nerve agent-induced seizures and lethality. Assessed pharmacokinetics of lead anticonvulsants against organophosphates. Refined animal models and validated small and large animal neurobehavioral test batteries. Investigated long-term neuroprotective strategies.</p> <p>FY 07 - Explore potential broad spectrum reactivators to nerve agent challenge (peripheral and centrally acting). Synthesize prospective candidate reactivators and conduct reactivation studies to determine efficacy and toxicity in vitro/in vivo. Optimize therapy for effective treatment of seizures under all potential field conditions (immediate or delayed treatment). Screen putative neuroprotectants that have demonstrated effectiveness in neuronal rescue, particularly Food and Drug Administration (FDA)-approved products which may have additional neuroprotective activity. Apply screening protocols to novel compounds.</p> <p>FY 08 - Expand the search for improved reactivators. Evaluate bioscavengers as post-exposure therapeutics against nerve agents. Further evaluate FDA approved products demonstrating neuroprotective activity for in vivo efficacy against nerve agent exposure.</p> <p>FY 09 - Identify and develop broad-spectrum improved reactivators based on the mechanism of action of reactivation. Down-select novel and FDA approved anticonvulsants, neuroprotectants, anti-epileptics, and receptor agonists and antagonists for neuroprotective activity against nerve agents. Define and optimize the utility of therapeutic bioscavengers.</p>	9656	8996	9345	9442
Therapeutics, Medical Toxicology - Non Traditional Agents (NTAs) and Other Agents -	0	3831	2235	2225
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Bullet Text (cont)	FY2006	FY2007	FY2008	FY2009
<p>FY 07 - Investigate the potential for transient or sustained systemic toxicity resulting from exposure to NTAs and selected chemical warfare agents. Identify mechanisms of toxicity and establish a scientifically-defendable quantitative means of predicting consequent health effect in human operators. Emphasis is placed on developing computational tools that extend the utility of laboratory data for improving operational risk assessment and countermeasure therapy design.</p> <p>FY 08 - Extend the fidelity of predictive and computational tools by expanding the scope of validation studies to include multiple classes of NTAs. Develop appropriate animal model systems for non-traditional modes of toxicity.</p> <p>FY 09 - Quantify the nature, scope, and time course of exposure/effects using biochemical, toxicological, physiological, and modeling methods as required for therapeutic and clinical strategy design.</p>	0	3831	2235	2225
<p>Therapeutics, Non Traditional Agents (NTAs) -</p> <p>FY 08 - Evaluate the efficacy of currently available therapeutics for treatment resulting from exposure to NTAs and selected chemical warfare agents. Focus on therapies for respiratory injury following inhalational exposure and non-cholinergic mediated neurological injury, using small animal models. Investigate the efficacy of the stoichiometric bioscavenger as a post-exposure therapy.</p> <p>FY 09 - Evaluate pre-existing and new commercially available compounds for respiratory and neurological injury in small animal models and begin transition to large animal models (e.g. non-human primate). Initiate testing of novel compounds as therapies in small animal models. Define and optimize the utility of therapeutic bioscavengers against NTAs.</p>	0	0	9817	9666

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BUDGET ACTIVITY RDT&E DEFENSE-WIDE/ BA2 - Applied Research	PE NUMBER AND TITLE 0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	PROJECT TC2
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Accomplishments/Planned Program (Cont):	FY2006	FY2007	FY2008	FY2009
<p>Therapeutics, Animal Models -</p> <p>FY 06 - Developed a non-human primate percutaneous testing model for chemical warfare agent exposure. Assessed an alternate non-human primate model by determining basic immunological and physiological parameters and validating literature findings in order to demonstrate a mechanistic bridge to humans. Evaluated the non-human primates, and the Marmoset, as alternate non-human primate models by: determining the toxicity of nerve agents sarin, tabun, cyclosarin, VX, VR, and selected NTAs; determining the efficacy of currently licensed medical countermeasures against this panel of chemical warfare agents.</p> <p>FY 07 - Improve advanced non-human primate testing for chemical warfare agent exposure. Evaluate alternate models to meet FDA rules in a cost-effective manner. Transitions to other thrust areas in FY08.</p>	471	1045	0	0
Total	15728	19994	27341	27210

	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>
SBIR/STTR	0	298	0	0

Accomplishments/Planned Program	FY2006	FY2007	FY2008	FY2009
SBIR - FY 07 - Small Business Innovative Research.	0	298	0	0
Total	0	298	0	0

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BUDGET ACTIVITY RD&E DEFENSE-WIDE/ BA2 - Applied Research	PE NUMBER AND TITLE 0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	PROJECT TC2
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<u>C. Other Program Funding Summary:</u>	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>	<u>FY 2010</u>	<u>FY 2011</u>	<u>FY 2012</u>	<u>FY 2013</u>	<u>To Compl</u>	<u>Total Cost</u>
TC3 MEDICAL CHEMICAL DEFENSE (ATD)	20499	18225	28976	28526	29218	30777	31833	32133	Cont	Cont

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BUDGET ACTIVITY RDT&E DEFENSE-WIDE/ BA2 - Applied Research	PE NUMBER AND TITLE 0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	PROJECT TR2
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	COST (In Thousands)	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012	FY 2013	Cost to	Total Cost
		Actual	Estimate	Complete							
TR2	MEDICAL RADIOLOGICAL DEFENSE (APPLIED RESEARCH)	1258	1570	1990	1990	1990	1990	1990	1989	Continuing	Continuing

A. Mission Description and Budget Item Justification:

Project TR2 MEDICAL RADIOLOGICAL DEFENSE (APPLIED RESEARCH): This area funds applied research to develop pretreatments for providing an effective medical defense against validated radiological threats. Innovative technical approaches and advances will be utilized to mitigate the health consequences from exposures to ionizing radiation which would represent a significant threat to US forces in current tactical, humanitarian, and counter terrorism mission environments. New protective and therapeutic strategies will broaden the military commander's options for operating within nuclear or radiological environments by minimizing both the short- and long-term risks of radiation exposure. Accurate models to predict casualties will promote effective command decisions and force structure planning.

B. Accomplishments/Planned Program

	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>
Congressional Interest Items	971	0	0	0

Accomplishments/Planned Program	FY2006	FY2007	FY2008	FY2009
Radioprotectants, Advanced Neutron Radiography - FY 06 - Delivered a laboratory prototype of a neutron radiography system that would support the development of a field-deployable, high-capability, neutron radiography system operable by military personnel, without exceptional training.	971	0	0	0
Total	971	0	0	0

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BUDGET ACTIVITY RDT&E DEFENSE-WIDE/ BA2 - Applied Research	PE NUMBER AND TITLE 0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	PROJECT TR2
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	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>
Radioprotectants	287	1555	1990	1990

Accomplishments/Planned Program	FY2006	FY2007	FY2008	FY2009
<p>Radioprotectants -</p> <p>FY 06 - Identified four agents for radioprotective efficacy studies in a rodent model.</p> <p>FY 07 - Continue radioprotective efficacy studies and explore additional new compounds for radioprotective efficacy studies. Assess the more promising candidates to determine the radiological treatment dose efficacy for radioprotection and develop protocols for evaluation in a rodent model system. Assess cytokine expression in rodents for most promising candidates against acute radiation syndromes.</p> <p>FY 08 - Evaluate three to four drug candidates for radioprotective efficacy. Using promising candidates, initiate preliminary studies for preclinical efficacy of combined agents, if any, which confer protective or palliative effects against radionuclides with minimal toxic side effects.</p> <p>FY 09 - Continue to evaluate at least two promising drug candidates promising radioprotective efficacy. Determine the preclinical efficacy of combined agents that confer protective or palliative effects against radionuclides with minimal toxic side effects. Explore current Good Laboratory Practice (cGLP) test capability for selected candidate drugs against acute radiation syndromes according to the Food and Drug Administration (FDA) animal rule.</p>	287	1555	1990	1990
Total	287	1555	1990	1990

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BUDGET ACTIVITY RDT&E DEFENSE-WIDE/ BA2 - Applied Research	PE NUMBER AND TITLE 0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	PROJECT TR2
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	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>
SBIR/STTR	0	15	0	0

Accomplishments/Planned Program	FY2006	FY2007	FY2008	FY2009
SBIR - FY 07 - Small Business Innovative Research.	0	15	0	0
Total	0	15	0	0

C. <u>Other Program Funding Summary:</u>	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>	<u>FY 2010</u>	<u>FY 2011</u>	<u>FY 2012</u>	<u>FY 2013</u>	<u>To Compl</u>	<u>Total Cost</u>
TR3 MEDICAL RADIOLOGICAL DEFENSE (ATD)	0	2153	2189	4825	2487	995	0	0	0	12649