CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2 Exhibit)

DATE: **February 2006**

BUDGET ACTIVITY: **RDT&E DEFENSE-WIDE/ BA2 - Applied Research**

PE NUMBER AND TITLE: **0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**

COST (In Thousands)		FY 2005 Actual	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	FY 2010 Estimate	FY 2011 Estimate	Cost to Complete	Total Cost
	Total Program Element (PE) Cost	172120	246953	280422	214036	191991	173790	166261	Continuing	Continuing
CB2	CHEMICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)	104707	134222	103092	95674	91186	84402	80623	Continuing	Continuing
TB2	MEDICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)	42987	88779	145073	76474	54837	43864	41114	Continuing	Continuing
TC2	MEDICAL CHEMICAL DEFENSE (APPLIED RESEARCH)	24426	23657	30682	38927	41418	40598	39136	Continuing	Continuing
TR2	MEDICAL RADIOLOGICAL DEFENSE (APPLIED RESEARCH)	0	295	1575	2961	4550	4926	5388	Continuing	Continuing

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2 Exhibit)	DATE February 2006
BUDGET ACTIVITY **RDT&E DEFENSE-WIDE/** **BA2 - Applied Research**	PE NUMBER AND TITLE **0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**

A. <u>Mission Description and Budget Item Justification:</u> 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.

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2 Exhibit)

DATE: **February 2006**

BUDGET ACTIVITY: **RDT&E DEFENSE-WIDE/ BA2 - Applied Research**

PE NUMBER AND TITLE: **0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**

B. Program Change Summary:		FY 2005	FY 2006	FY 2007
Previous President's Budget (FY 2006 PB)		168827	187787	179914
Current Biennial Budget Estimate (FY 2007)		172120	246953	280422
Total Adjustments		3293	59166	100508
a. Congressional General Reductions		-131	-3604	0
b. Congressional Increases		0	62770	0
c. Reprogrammings		4806	0	0
d. SBIR/STTR Transfer		-1382	0	0
e. Other Adjustments		0	-25	100508

Change Summary Explanation:

Funding: FY06 - Congressional increases to enhance projects within the science and technology base (+$31,920K CB2; +$30,850K TB2). Congressional general reductions and other adjustments (-$2,015K CB2; -$1,175K TB2; -$409K TC2; -$5K TR2).

FY07 - Increase to enhance Medical Biological research efforts in support of the Transformational Medical Technology Initiative which focuses on broad-spectrum defenses against intracellular bacterial pathogens and hemorrhagic fevers (+$101,900K TB2). Defense-wide directed offsets (-$3,086K CB2; -$1,249K TB2; -$918K TC2; -$47K TR2). Inflation adjustment (+$1,437K CB2; +$2,021K TB2; +$428K TC2; +$22K TR2).

Schedule: N/A

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2 Exhibit)

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BUDGET ACTIVITY
RDT&E DEFENSE-WIDE/
BA2 - Applied Research

PE NUMBER AND TITLE
0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)

Technical: N/A

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)

DATE: **February 2006**

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**CB2**

COST (In Thousands)		FY 2005 Actual	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	FY 2010 Estimate	FY 2011 Estimate	Cost to Complete	Total Cost
CB2	CHEMICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)	104707	134222	103092	95674	91186	84402	80623	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-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 operation 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. Research in this PE also supports the Joint Requirements Office (JRO) for CB Defense Baseline Capability Assessment.

B. Accomplishments/Planned Program

	FY 2005	FY 2006	FY 2007
Congressional Interest Items	43297	31617	0

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)	DATE February 2006

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**CB2**

FY 2005 Accomplishments:

- 992 Agent Detection and Neutralization System (AFSOC) - Evaluated the capability of DNA Capture Elements (DCEs) provided by Conceptual MindWorks, Inc. as biological warfare agent sensor(s) for live anthrax spores, as well as other existing antibody-based sensors, to perform under battlefield conditions and determine the sensitivity, responsiveness and robustness of these biological sensors.
- 2479 CBRN Countermeasures - Conducted research that focuses on human exposures to bacterial/viral/toxin agents, chemical warfare agents, toxic industrial chemicals, or radioisotopes from aerosol releases associated with terrorist incidents in urban and near-urban environments. Concentrated efforts that expand the knowledge, tools, models, and strategies necessary to protect against WMD. Conducted laboratory studies of cell type-specific, cytotoxic effects and mechanism of lethality for biomedical applications; conducted dispersion modeling, exposure estimation, and risk assessment of aerosol releases for in-door and ambient environments for threat characterization; developed model emergency medical systems for responsiveness to terrorist incidents as part of consequence management; and assessed social psychological/psychiatric dimensions of behavioral dynamics to prevent or respond to terrorism.
- 2157 Chemical Agent Persistence Models - Conducted Independent Verification and Validation (IV&V) of CB models, simulations, and battlespace management tools for environmental fate of agents, Chemical Hazard Estimation Risk Assessment Tool (CHEMRAT) version 1.5 and other models as applicable to chemical-biological defense.
- 992 IMS Sample Concentration and Bioagent Detection - Developed a front-end to allow the sample collection and process to increase the performance of existing detection technologies.

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)	DATE February 2006

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**CB2**

FY 2005 Accomplishments (Cont):

- 992 Integrated Biodefense Research - Developed technologies for rapid response to airborne biological and chemical agents in battlefield and key urban environments. Developed new methods for the production of nanometer - and micrometer-sized crystals of organic materials.
- 1488 Low-cost Automated Gas Chromatograph/Flame Photometric Detector System - Developed an inexpensive chemical agent detector based on gas chromatograph and atomic emission spectroscopy from chemical agents.
- 1488 Systems for Sampling and Detecting Bioaerosols - Developed a low cost, front-end for sample collection and processing of biological materials for the next generation of light weight biological detectors.
- 992 Agent Fate Program - Conducted Verification and Validation (V&V) task for modeling work in DTO CB42, Environmental Fate of Agents.
- 992 Air Contamination Monitoring System - South Coast Air Quality Management District (SCAQMD) - Developed and validated concepts of operation for the protection of high value/visible domestic facilities, i.e. sports arena. Provided sufficient equipment to support and demonstrate the concepts of operation.
- 1488 Biological-Chemical Vaporous Hydrogen Peroxide Decontamination for Military Aircraft and Equipment - Validated the adaptation of biological-chemical vaporous hydrogen peroxide in performing fast and effective decontamination of military aircraft.

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BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**CB2**

FY 2005 Accomplishments (Cont):

- 3719 Chemical-Biological Protective Suit Membrane Research - Continued optimization of membrane materials to increase moisture vapor transport and durability and to reduce chemical warfare agent permeation. Fabricated optimized membrane into candidate fabric systems for further evaluation. Conducted laboratory evaluations of candidate fabric systems.
- 3471 Chemical Imaging for Food and Water Safety - Developed an imaging capability based on Raman spectroscopy to detect biological contaminants in food and water.
- 992 Early Warning and Detection Program - Developed new point sensors based on surface enhanced Raman using semi-metallic oxide materials to detect the biological materials.
- 1289 Future Force Warrior-Nano Wire Mesh Fabrics for Chemical-Biological Agent Defense - Fabricated barrier materials employing wire mesh technology and assessed their efficacy against chemical warfare agent simulants. Down-selected best candidate material configurations and optimized to improve protective barrier characteristics. Conducted assessment of optimized materials against simulants and chemical warfare agents.
- 3719 Low Cost Chemical-Biological Protective Shelter Development - 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 most promising technologies and initiated evaluation of those technologies for target applications.
- 4166 Love Shear Horizontal Surface Acoustic Wave (LSH-SAW) Hand-held Biosensor - Developed a light-weight handheld biological sensor based on the use of antibodies supported on quartz resonators.

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DATE: **February 2006**

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**CB2**

FY 2005 Accomplishments (Cont):

- 992 Remote Optical Sensing Program - Developed new optical components base on semi-metallic oxide materials to replace conventional mechanical components currently used in detector systems.
- 992 Research on a Molecular Approach to Hazardous Materials Decontamination - Conducted research into the use of multi-phase systems for decontamination. Evaluated the combinations of agent/surfactant/water and agent/solid/surfactant/water.
- 1190 Technology for the Protection of Air and Water Systems - Developed technology to detect the presence of chemical and biological contaminants in water.
- 1984 Zumwalt Program for Countermeasures to Biological and Chemical Threats - Developed new models and sensor systems for the detection and identification of chemical and biological hazardous materials.
- 1984 Real-Time Non-Specific Viral Agent Detection - Developed and published the operating protocols for at least four non-enveloped viruses from naturally occurring sources using the VDSC-1 virus detection technology.
- 2681 Chemical Biological Defense Program Initiative Fund.
- 2058 Conducted independent audit of CBDP financial statements. Conducted studies and analysis of the Guardian Installation Protection Program capabilities and options. Performed program reviews/assessments including congressional issue analysis.

Total 43297

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DATE: **February 2006**

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**CB2**

FY 2006 Planned Program:

- 1040 Chem-Bio Disinfection/Neutralization Effort.
- 991 Immuno-Array.
- 991 IMS Sample Concentration and Bioagent Detection.
- 3466 Low-Cost Protective Chem-Bio Shelters - Conduct 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-select candidates to most promising technologies and initiate evaluation of those technologies for target applications.
- 991 Omni Spray Development of Desportion Electro-Spray Ionization (DESI).
- 1040 Quantum Fingerprint Technology for Chem-Bio Sensing.
- 991 Warfare Agents Program.
- 991 Real-Time Non-Specific Viral Agent Detector.
- 2842 Self Decontaminating Polymer System for Chemical and Biological Warfare Agents.
- 496 Theater Level Modeling of Chemical and Biological Operational Effects at the Level of Individual Soldier.
- 991 Vulnerability Determination for Air Vehicle Contamination.
- 1387 Zumwalt Program for Countermeasures to Biological and Chemical Threats - Continue Development of new models and sensor systems for the detection and identification of chemical and biological hazardous materials.
- 1387 Portable CB Detection Sensor System.

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DATE: **February 2006**

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**CB2**

FY 2006 Planned Program (Cont):

- 1585 Nanotechnology for Detection of BW Agents.
- 2476 Advanced Emergency Medical Response Training Program.
- 1585 Nanowire Mesh Fabrics for Chem/Bio Defense - Fabricate barrier materials employing wire mesh technology and assess their efficacy against chemical warfare agent simulants. Down-select best candidate material configurations and optimize to improve protective barrier characteristics. Conduct assessment of optimized materials against simulants and chemical warfare agents.
- 991 Research on Molecular Approach to Hazardous Materials Decontamination - Continue research into the use of multi-phase systems for decontamination. Evaluate the combinations of agent/surfactant/water and agent/solid/surfactant/water.
- 446 System for Bacterial Warfare Agent Detection.
- 6930 Chemical Biological Defense Program Initiative Fund.

Total 31617

	FY 2005	FY 2006	FY 2007
Decontamination	3932	6703	6006

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BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**CB2**

FY 2005 Accomplishments:

- 1714 Solution Chemistry BCA#17/18/23 - Concluded studies on activated sorbent suspensions in hydrofluoro ethers (HFE) solvent systems. Initiated a new effort to develop reactive impregnated solvent-based wiping systems. Initiated a new effort to develop a better filtration system for HFE solvent systems as a product improvement for the Joint Service Sensitive Equipment Decontamination (JSSED) acquisition effort. Continued research on electrochemical development of chlorine dioxide to develop a man-portable decontamination system to support Joint Portable Decontamination System (JPDS).
- 2218 Solution Chemistry - Oxidative Formulation (DTO CB44) BCA#18/23/34 - Completed chamber testing over operational temperature range, finished material compatibility testing, and formulated new oxidative approaches into a dry powder and/or concentrated liquid. This DTO supported the Joint Transportable Decontamination Systems (JSTDS) and JPDS requirements. Completed DTO in FY05.

Total 3932

FY 2006 Planned Program:

- 1115 Process Fundamentals BCA#17/18/23/34 - Initiate new research efforts to develop an aerosol-based decontamination application and determine the efficacy effects using highly effective aerosolized activated hydrogen peroxide. Continue 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.

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BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**CB2**

FY 2006 Planned Program (Cont):

- 3034 Solution Chemistry BCA#17/18/23 - Conclude development of a chlorine dioxide based man-portable decontamination system and investigate alternative solution based technologies for developing chlorine dioxide to support JPDS; continue efforts to develop reactive impregnated solvent-based wiping system capable of decontaminating vehicle interiors and sensitive equipment to support JSSED and Joint Platform Interior Decontamination (JPID); initiate new review of technologies for point-of-use generation of hydrogen peroxide for use in a variety of decontamination applications to support JSTDS.
- 375 Solid Phase - Continue to develop porous polymer solvent cartridges for removing CW agents from fluorinated solvents used in sensitive equipment decontamination as a JSSED incremental improvement.
- 2179 Alternative Process BCA#17/18/23/24/39 - Initiate new research to develop a gaseous chemical and biological decontamination system combined hot air and modified vaporous hydrogen peroxide and determine efficacy effects on decontamination of chemical and biological agents and transition to BA3 to support JSTDS, JPID, and JSSED; and initiate new studies to determine technical potential of reactive coatings to enhance decontamination efficacy.

Total 6703

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BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**CB2**

FY 2007 Planned Program:

- 1100 Process Fundamentals BCA#17/18/23/34 - Complete research efforts to develop an aerosol-based decontamination application and determine the efficacy effects using highly effective aerosolized activated hydrogen peroxide.
- 2257 Solution Chemistry BCA#17/18/23/34 - Complete development of reactive impregnated solvent-based wiping system and transition to Joint Platform Interior Decontamination (JPID); initiate new research on technologies to develop hydrogen peroxide at their point-of-use; and continue efforts/initiate new research to develop an improved decontamination solution that is reactive, non-corrosive, environmentally benign, and effective on a multitude of surfaces.
- 1264 Solid Phase BCA#17/18/34 - Complete development of an improved filtration system for hydrofluoro ethers solvent cleaning systems and transition to the Joint Service Sensitive Equipment Decontamination System (JSSED) program as a product improvement; and continue efforts/initiate new research to develop reactive sorbent decontaminants with an added focus on nano-based technologies.
- 1385 Alternative Process BCA#17/18/34/39 - Continue efforts/initiate new research to demonstrate decontamination processes using gas, kinetic, energetic, and/or novel approaches to develop new decontaminants and decontamination processes; and continue studies to determine technical potential of reactive coatings to enhance decontamination efficacy.

Total 6006

	FY 2005	FY 2006	FY 2007
Detection	12673	21831	23025

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BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**CB2**

FY 2005 Accomplishments:

- 5104 Stand-off Biological Aerosol Detection (DTO CB35) BCA#1 - Evaluated breadboards in field environments to detect and discriminate (biological vs. non-biological) biological and chemical agents at concentration of 1,000 agent containing particles per liter of air (ACPLA) at a range of 1 km. Conducted feasibility studies to enhance false alarm to one per week and to operate during daytime. This DTO supports the Joint Biological Stand-off Detection Systems (JBSDS).
- 2000 Wide Area Aerial Reconnaissance for Chemical Agents (DTO CB53) BCA#28 - Developed a 3-Hz, 128 x 128 tunable Adaptive Infrared Imaging Spectroradiometer (AIRIS). Performed sensor characterization tests. Developed off-line algorithms and signal processing techniques. This DTO supports the Joint Service Light Nuclear Biological Chemical Reconnaissance System (JSLNBCRS) and Stryker programs.
- 5569 Point Detection, Integrated CB BCA#28 - Continued development of first generation breadboard based on millimeter wave spectroscopy for bio detection. Initiated Raman spectroscopy for the detection/identification of biological materials. Expanded effort from Lightweight Integrated CB Detection (DTO CB50) on aerosol properties for identification of chemicals.

Total 12673

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RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**CB2**

FY 2006 Planned Program:

- 4700 Stand-off Biological Aerosol Detection (DTO CB35) BCA#1 - Demonstrate 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. Evaluate the feasibility of the demonstrated technology to also meet the chemical stand-off detection requirements. This DTO completes in FY06 and supports the Joint Biological Stand-off Detection Systems (JBSDS).
- 4000 Wide-Area Aerial Reconnaissance for Chemical Agents (DTO CB53) BCA#28 - Determine optimum spectrometer performance specifications in terms of scan speed, spatial resolution, and spectral resolution. Demonstrate an enhanced Fourier Transform Infrared (FTIR) and tunable IR systems with real-time data processing on an airborne platform in a reconnaissance application using the appropriate performance parameters. Complete DTO. This DTO supports the Joint Service Light Nuclear Biological Chemical Reconnaissance System (JSLNBCRS) and Stryker vehicle programs.
- 5101 Point Detection, Integrated CB BCA#28 - Continue first generation breadboard based on millimeter wave spectroscopy for bio detection. Continue Raman spectroscopy for the detection/identification of biological materials. Initiate investigations in solid state visible and UV receivers to replace photomultiplier tube for improved size, weight, power, reliability, and cost. Initiate microelectronic machine sized solid state FTIR point sensor system.
- 2100 Detection of CB Contamination on Surfaces BCA#31/33 - Initiate the development of technology to meet the needs to detect contamination on surfaces in a post decontamination application.

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RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**CB2**

FY 2006 Planned Program (Cont):

- 2431 Point Detection, Biological Identification BCA#21 - Leverage efforts from Medical Science and Technology programs in proteomics for biomarkers for the identification of biological agents in complex biological backgrounds.
- 3499 Biological and Chemical Stand-off Technology BCA#1/7 - Initiate the development of models to predict passive standoff technology responses to aerosols. Initiate detection modalities to detect sentinel species from biological chemical warfare materials and processes. Initiate studies to investigate the optimal performance parameters for hyperspectral technology to detect biological materials. Initiate studies to optimize/convert detection algorithms to imaging technology.

Total 21831

FY 2007 Planned Program:

- 6755 Point Detection, Integrated CB BCA#28 - Complete and demonstrate first generation breadboard based on millimeter wave spectroscopy for bio detection. Evaluate the millimeter wave breadboard to determine the availability of biological signatures. Complete Raman spectroscopy for the detection/identification of biological materials.
- 4000 Detection of CB Contamination on Surfaces BCA#31/33 - Continue the development of technology to meet the needs to detect contamination on surfaces in a post decontamination application.
- 4000 Biological Identification BCA#21 - Continue the development of proteomics to identify biomarkers for the identification of biological agents in complex biological backgrounds.

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RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**CB2**

FY 2007 Planned Program (Cont):

- 5000 Chemical Point Detection BCA#20/33 - Continue the development of a micro gas analyzer with technology from DARPA. 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).
- 3270 Biological and Chemical Stand-off Technology BCA#1/7 - 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. Initiate studies to optimize/convert detection algorithms to imaging technology.

Total 23025

	FY 2005	FY 2006	FY 2007
Modeling and Simulation Battlespace Management	8263	30257	26328

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RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**CB2**

FY 2005 Accomplishments:

- 1154 Chemical and Biological Hazard Environment Prediction (DTO CB55) and Hazard Prediction with Nowcasting (DTO CB62) - Continued refinement of MESO code for transition to Joint Effects Model (JEM). Performed independent validation and verification of a computation fluid dynamics - based tools set. Continued DTO CB62 to enhance near-surface environmental characterization and demonstrate improvements using the Joint Effects Model (JEM).
- 2795 CBDP Decision Capability (formerly Simulation Based Acquisition) - Completed tool design and began prototype construction and testing. Consolidated analytic library and analysis methodology for use by program for rapid decision making. Used iterative user-focused design techniques to enhance tool/capability usability and acceptance.
- 1950 Battlespace Management - Continued efforts to optimize data fusion and decision-making across networks and to provide visualization of network sensor responses within the current and planned Command, Control, Communications, Computers, Intelligence, Surveillance, and Reconnaissance (C4ISR) architecture frame work. Integrated existing models into the Global Information Grid (GIG) and Net-Centric Enterprise System (NCES).
- 2364 Chemical and Biological Warfare Effects on Operations (DTO CB43) - Tested and transitioned to Joint Operational Effects Federation (JOEF) transition. Developed mobile forces module. Conducted internal Verification and Validation (V&V). Completed DTO.

Total 8263

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RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**CB2**

FY 2006 Planned Program:

- 9215 Chemical and Biological Warfare Effects on Operations (non-DTO) BCA#5/6/8/9 - Identify new applications for the Joint Operational Effects Federation (JOEF). Implement Mission-Oriented Protective Posture (MOPP) capabilities and integrate the biological agent toxicity model into the military worth assessment toolkit. Begin development of an operational impact assessment tool. Start and complete the requirements generation for the linkage of the Simulated Training and Analysis for Fixed Facilities/Sites (STAFFS) and CONTAM models. Begin model design and development of Chemical-Improvised Explosive Device (C-IED) effects model. Conduct a side-by-side comparison of mobile force models for inclusion in JOEF. Improve CBR operational effects modeling tools and methods by working with various agencies/labs to identify capabilities and areas for follow-on research/development. Begin development activities for the integration of JOEF components with theater-level models such as the Joint Integrated Contingency Model (JICM).
- 7300 Chemical and Biological Hazard Environment Prediction (DTO CB55) BCA#3/5/6/8 - Complete DTO CB55. Continue high altitude intercept effects characterization by understanding and modeling key physics for single drops. Continue littoral and maritime effects model for JEM by constructing and testing a coastal tracer release system. Conduct study of computation modeling for urban flows. Conduct study of NTA transport and dispersion module requirements for JEM. Conduct verification, validation and documentation of the knowledge based approach for intelligent sensor control and networking. Adapt and integrate existing cellular automata models into a Geographic Information System (GIS) tool for hazard assessment. Validate FAST3D-CT model with wind tunnel data.

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RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**CB2**

FY 2006 Planned Program (Cont):

- 2400 Sensor Data Fusion - Hazard Prediction with Nowcasting (DTO CB62) BCA#5/6 - Enhance near-surface environmental characterization and demonstrate improvements using the Joint Effects Model (JEM). Consolidate source term determination module development. Assess and select appropriate methods for integrating near real-time weather data into transport and dispersion models. Enhance interface between JEM and mesoscale model. Deliver report on complex environments and algorithm refinement. Demonstrate CB source determination module. Validate and complete documentation. Further develop the preferred method for using specific data from chemical and biological sensors to determine hazard source. Develop and test the SCIPUFF Adjoint Model using ideal observational data.
- 6850 Battlespace Management BCA#2/3/4/8/9 - Design Net-Centric Enterprise Systems (NCES) modules for migration to test environment. Develop 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. Conduct study of user interface requirement for future indications and warning for CBRN hazards in both deployed force and homeland defense scenarios. Develop integration strategy to link consequence management capability into Joint Warning and Reporting Network (JWARN). Begin development of appropriate bridging capability to extend JWARN capabilities to homeland defense architectures. Begin development of a modeling/exercise rehearsal capability for JWARN. Field test intelligent agent decision. Provide an integrated demonstration and user access for the Shared Common Operating Picture (COP). Conduct live real-time demonstration of JWARN Compliant Interface Device (JCID) compliant thin server on examples of fielded JWARN sensors. Continue work on web services, NCES and GIG integration for common CBRN software services. Demonstrate inter-LAN socket connection manager in a simulated network environment.

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)	DATE February 2006

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**CB2**

FY 2006 Planned Program (Cont):

- 4492 CBDP Decision Capability BCA#1-39 - Continue building the analytical framework. Begin development of a representative sensor prototype model. Continue to identify gaps in capability to conduct rapid program analysis and conduct feasibility assessments for tool(s) development. Begin development of selected model and database linkages between analytic framework and decision support personnel. Demonstrate the architecture of the multivariate decision support tool and develop a prototype. Develop High Level Architecture (HLA) federates and components for the CB urban experimental and evaluation simulation.

Total 30257

FY 2007 Planned Program:

- 9863 Chemical and Biological Warfare Effects on Operations (non-DTO) BCA#5/6/8/9 - 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-Improvised 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 CONTAM model linkages. Test and verify software upgrades.

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)	DATE February 2006

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	CB2

FY 2007 Planned Program (Cont):

- 4879 Chemical and Biological Hazard Environment Prediction (non-DTO) BCA#3/5/6/8 - Complete development of data assimilation techniques to improve forecasts of near-surface characteristics important for hazard prediction. Complete development of modules for Joint Effects Model (JEM) for high altitude, urban, littoral and coastal environments, and indoor scenarios. Integrate and field test sensor data fusion efforts with JEM. Model key physics for large scale events for the high altitude intercept module. Continue the development of a test-bed for transport and dispersion modeling. Conduct two week coastal and littoral meteorological and tracer concentration measurement program for coastal & littoral dispersion. Provide validation procedures for urban contaminant transport models. Validate wind tunnel and FAST3D-CT with OKC field trial data. Provide validation report. Develop/integrate/test new Cellular Automat CBR specific models. Evaluate mesoscale model forecasts using available observations for improved coastal urban dispersion prediction.
- 2400 Sensor Data Fusion - Hazard Prediction with Nowcasting (DTO CB62) BCA#5/6 - Complete DTO CB62. Integrate improved near-surface meteorological forecast capabilities into JEM. Deliver final report and computational implementation of preferred algorithm(s) for source term estimation. Test sensor placement software suite against existent data. Develop Graphical User Interface (GUI) and Application Program Interface (API). Begin selection of best source term estimation tool.

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)

DATE: **February 2006**

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**CB2**

FY 2007 Planned Program (Cont):

- 6500 Battlespace Management BCA#2/3/4/8/9 - Build Net-Centric Enterprise Systems (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 Joint Warning And Reporting Network (JWARN) related sensors and nodes. Begin test of CBRN interfaces to assess impact on JWARN and other Command, Control, Communications, Computers, Intelligence, Surveillance, and Reconnaissance (C4ISR) entities. Begin preliminary research on alternative CBRN display technologies. Continue sensor-data fusion and source term location technologies with eventual integration with Joint Effects Model (JEM) and Joint Operational Effects Federation (JOEF).
- 2686 CBDP Decision Capability BCA#1-39 - Continue building the analytical framework. Continue to identify gaps in capability to conduct rapid program analysis and conduct feasibility assessments for tool(s) development. Begin 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 JSAF plug-ins and Urban Resolve capability for the urban experimental and evaluation simulation. Transition capability.

Total 26328

	FY 2005	FY 2006	FY 2007
Protection	8664	10645	10311

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)	DATE February 2006

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**CB2**

FY 2005 Accomplishments:

- 1355 Advanced Air Purification System Model (DTO CB61) BCA#11 - Developed conceptual modules for Advanced Air Purification Systems Model. Developed draft matrices for air purification systems that can address wide application requirements by providing the optimal mix of technologies. Model incorporates mature unit processes for the purpose of providing broader protection than current single pass filter technology. Performed testing on lab-scale systems measuring performance data.
- 1249 Collective Protection, Air Purification BCA#11- Characterized and optimized performance of single pass filters using advance chemical sorbents and aerosol/particulate removal processes. Terminated study of toxic industrial chemical degradation of High Efficiency Particulate Arresting (HEPA) filters due to change in requirements. Developed advanced air purification technology demonstrators based upon temperature swing adsorption and electrical swing adsorption approaches and integrated with environmental control units. Leveraged developmental residual life indicator hardware and completed initial chemical pulsing concepts to probe filter adsorbent capacity.
- 1098 Collective Protection, Shelters BCA#11- Explored airlock concepts focusing on improved airflow properties and ease of use features using computer modeling as well as purge testing. Novel CB closures were fabricated, tested and down-selected to the best performing concept for further development and testing. Continued development of new impermeable CB resistant barrier material, starting with a front-end analysis and identification of conceptual configurations leading to prototype shelter system using newly developed shell material. Performed simulant and agent testing on cloth swatches treated with self-decontaminating chemistries. Demonstrated overpressure performance of expedient coating formulations to reduce leakage and conducted chemical permeability testing of the formulations.

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)	DATE February 2006

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**CB2**

FY 2005 Accomplishments (Cont):

- 972 End-of-Service-Life Indicators (ESLI) for NBC Mask Filters (DTO CB36) BCA#19 - Selected color-change technology was successfully demonstrated in filter test beds. Modified commercial respirator cartridges and Joint Service General Purpose Mask (JSGPM) filter elements to assess ESLI prototype baseline performance against the target CWAs. The ESLI proved to be an effective colorimetric indicator for certain high-priority toxic industrial chemicals (e.g., chlorine and sulfur dioxide). Tests conducted to evaluate ESLI service life and shelf life successfully demonstrated the ability of the technology to meet the climatic operational and storage performance requirements for the Joint Service General Purpose Mask (JSGPM). The ESLI technology is transitioning to the JSGPM.
- 1100 Respiratory Protection-Enhanced Chemical and Biological Radiological and Nuclear (CBRN) BCA#19; Non Traditional Agents (NTA); and Toxic Industrial Chemical (TIC) Protection - Developed final concepts for active and passive pressurization. Several advanced mask concepts were completed and presented for comment to both the user and acquisition communities at a workshop in August 2005. Bio protection factor (PF) test procedures were validated, a human bio-PF study conducted, and a final report prepared. The bio-PF test protocol and apparatus is now available for evaluating current and future masks. Results of these efforts will be used for the assessment of current masks, and in the development of future masks.
- 1344 Self-Detoxifying Materials for Chemical/Biological Protective Clothing (DTO CB45) BCA#26 - Down-selected materials from DTO studies as well as auxiliary projects (Congressionals, DARPA projects, and SBIRs). Down-selected materials - chloramines are multifunctional; nanoparticles of Al2O3 and TiO2 are promising. POM catalysts were optimized. New permselective membranes were assessed in addition to nanofiber membranes.

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)	DATE February 2006

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**CB2**

FY 2005 Accomplishments (Cont):

- 395 Individual Protection Percutaneous Protection BCA#27 - Reduced Physiological Burden - Developed and evaluated the performance of prototype intermittent microclimate cooling system components. This technology supports future protective ensembles.
- 1151 Individual Protection, Percutaneous Protection, Enhanced Protection (Aerosol NTAs and Bio) BCA#26 - Prepared and evaluated carbon-loaded fabric with nanofiber and membrane backing suitable for fabrication into prototype garments. Developed and evaluated advanced closure concepts and initiated fabrication of optimized closure candidates. Developed swatch test technology for assessing the role of wind speed in challenging penetration of individual protection equipment. Resulting technologies/knowledge will transition to support future protective ensemble.

Total 8664

FY 2006 Planned Program:

- 700 Advanced Air Purification System Model (DTO CB61) BCA#11 - Configure laboratory-scale systems, define test and evaluation methodology, and measure the required design and system integration data (characterize unit processes). Develop initial version of Advanced Air Purification System Model.
- 1042 Improved Single-Pass Filters BCA#11 - 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. Develop chemical probes, hardware and methodology to assess residual life indicator Collective Protection (COLPRO) chemical filters. Assess and report the impact of particle size distribution and long-term loading by measuring efficiency changes on aerosol/particulate flat sheet HEPA media and full size HEPA filters.

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BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	CB2

FY 2006 Planned Program (Cont):

- 1385 Regenerative and Reactive Air Purification BCA#11 - Perform lab-scale studies of two and four bed Temperature, Pressure, and Electrical Swing Adsorption regenerative air purification systems. Initiate new evaluations of three competing Electrical Swing Adsorption technologies by constructing equivalent test stands. Apply temperature and pressure regenerative system technology to DTO CB61 and then to Joint Expeditionary Collective Protection (JECP) Technology Readiness Evaluation (TRE) in FY08. Initiate new development of reactive air purification technologies.
- 1385 Shelter Materials, Coatings and Materials Treatments, Reactive or Self-Decontaminating BCA#11 - Continue the development of expedient protective coatings, determine material interactions and permeability and perform conceptual soft shelter testing. Develop a family of coatings that will form a gas impermeable film for expedient encapsulation and CB hardening of existing structures. Initiate new development of microcrystalline and nanocrystalline cellulose materials for use with reactive chemistries.
- 1375 Shelter Systems and Contamination Control Area (CCA)/Airlock/Toxic Free Area (TFA) (CCAATFA) BCA#19 - Advance and integrate collective protection shelter system technologies for airlocks, CB closures, CB barriers (impermeable and permeable reactive) and seaming. Develop a regenerable reactive coating that is thin and flexible that will neutralize chemical and biological warfare agents upon contact. For CCAATFA processing convene working group to analyze threat, systems and current protocol; perform initial Computational Fluid Dynamics (CFD) airflow analysis, testing and generate interim report detailing CCAATFA processing.

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)

DATE: **February 2006**

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**CB2**

FY 2006 Planned Program (Cont):

- 1773 Respiratory Protection-Enhanced CBRN/NTA/TIC Protection BCA#27 - Complete trade-off analysis and initiate fabrication of advanced mask concept prototype models. Trade-off analysis will be conducted and down-selects made of the most promising technologies for protection enhancement. This will include intelligent seals and may also include micro-reactors for air purification, micro-thermoelectric system for cooling, and active air management systems for comfort and protection. Develop and evaluate a dual-cavity sealing system for insertion into selected mask platform.
- 1010 Individual Protection, Percutaneous Protection, Reduced Physiological Burden BCA#27 - Complete development of the Pulsed Microclimate Cooling System (PMCS), conduct bench-top, and human physiological testing, and transition to Army Technology Objective (ATO[R] NSC-03) Soldier Borne Microclimate Cooling Technologies, and other programs for further development. Conduct laboratory testing of breadboard metal hydride cooling system to assess thermal characteristics. Demonstrate selective and responsive nanopore-filled membranes synthesis concept, and encapsulated nanofiber mesh membranes fabrication. Measure permeability response of concept membranes as a function of electrical stimuli. Synthesize polymers and blends for application in elastomeric permselective membranes, evaluate water vapor and stimulant permeation, and model polymer molecular dynamics. Technologies support future protective ensembles.

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DATE: **February 2006**

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**CB2**

FY 2006 Planned Program (Cont):

- 1596 Individual Protection, Percutaneous Protection, Enhanced Protection (Aerosol NTAs and Bio) BCA#26 - Down-select aerosol barrier materials and closure concepts, incorporate both into an initial prototype garment, and evaluate. Optimize materials, closures, and suit design based on results of the evaluation. Characterize Individual Protection Equipment (IPE) materials filter efficiency for particle sizes and wind speeds, assess effect of material geometry on filter efficiency, and correlate challenge deposition in IPE systems with swatch, component tests at elevated wind speeds. Develop lab-scale non-woven polymer membrane samples and evaluate to assess particle removal efficiency and air permeability. Resulting technologies/knowledge will transition to support future protection ensembles.
- 379 Individual Protection, Percutaneous Protection, Enhanced Protection (Liquid NTAs and TICs) BCA#26 - Identify candidate fibers as support structures for sorbents and reactives and initiate laboratory evaluation of prototype fabrics to assess physical and permeation characteristics. Conduct market research to identify innovative materials applicable to protective boots and gloves, and identify candidates for further consideration.

Total 10645

FY 2007 Planned Program:

- 500 Advanced Air Purification System Model (DTO CB61) BCA#11 - Develop several potential system configuration designs. Initiate development of test apparatus and methodology for Advanced Air Purification System Model.

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BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	CB2

FY 2007 Planned Program (Cont):

- 900 Improved Single-Pass Filters BCA#11 - Investigate adding ethylene oxide, nitrogen dioxide and carbon monoxide functionalities to CP filters. Transition polishing sorbent technology Pressure Swing Adsorption (PSA), Temperature Swing Adsorption (TSA) and Pressure/Temperature Swing APTSA Regenerable Collective Protection. Complete sorbent work and transition technology to enhance performance of single-pass filters, regenerative systems, to DTO CB61 and to Joint Expeditionary Collective Protection (JECP) FY08 TRE.
- 1926 Regenerative and Reactive Air Purification BCA#11 - Optimize Temperature Swing Adsorption (TSA) and ESA operating parameters, adsorber design and test. Demonstrate air purification technology based on SELective ionization and contaminant EXtraction (SELEX).
- 1165 Shelter Materials, Coatings and Materials Treatments, Reactive or Self-Decontaminating BCA#11 - 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.
- 1770 Shelter Systems and Contaminated Control Area (CCA)/Airlock/Toxic Free Area (TFA) (CCAATFA) - Identify novel technologies for application in the CCAATFA and develop initial CATFA processing system design.
- 800 Respiratory Protection-Reduced Physiological Burden BCA#19 - Identify data gaps necessary for correlating respiratory resistance with performance and conduct testing to resolve. Initiate model development for predicting performance from respiratory resistance. This effort fulfills a knowledge gap and supports all current and future mask efforts.

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DATE: **February 2006**

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**CB2**

FY 2007 Planned Program (Cont):

- 900 Individual Protection, Percutaneous Protection, Reduced Physiological Burden BCA#27 - Develop brass-board metal hydride cooling system and conduct laboratory testing to validate thermal analysis. Develop a database relating selectivity and electrical stimulus responsiveness of nanopore-filled membranes as a function of polymer-polymer nanocomposite structural and chemical attributes. 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.
- 1100 Individual Protection, Percutaneous Protection, Enhanced Protection (Aerosol NTAs and Bio) BCA#27 - Produce optimized second-generation prototype garment employing both aerosol barrier materials and advanced closures and evaluate. Based on results, produce a final concept garment for limited field-testing. Develop one m2 non-woven polymer membranes material, incorporate into a prototype fabric system and assess performance. Resulting technologies/knowledge will support future protection ensembles.
- 1250 Individual Protection, Percutaneous Protection, Enhanced Protection (Liquid NTAs and TICs) BCA#26 - Based on FY06 evaluations, optimize novel fiber/fabrics and conduct fabric characterization and stimulant permeation testing. Conduct preliminary physical and chemical testing of candidate materials for glove and boot applications and down-select to most promising candidates. Initiate new efforts to assess and mediate the effect of liquid NTAs on percutaneous protection. Technologies will support the Joint Chemical Ensemble.

Total 10311

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BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	CB2

	FY 2005	FY 2006	FY 2007
Threat Agent Sciences	27878	31852	37422

FY 2005 Accomplishments:

- 3250 Threat Agents and Simulants - Continued and expanded efforts to determine and validate new synthesis targets. Continued to fill data gaps relative to classical and novel threat agents, toxic industrial chemicals, and CW agent simulants. Continued to catalog agent properties in searchable database. Continued investigations of inhalation toxicity of NTAs.
- 2218 Biological Threat Agents - Continued to synthesize small quantities for defensive RDT&E, toxicologically screened, characterized and identified new threat materials and filled identified data gaps for established biological threat agents. Continued to characterize fundamental properties of Y. pestis and initiate work on B. mallei. Completed characterization of fundamental properties of a viral family and continued characterization of a second viral family selected by biodefense priorities. Completed improvement of Erwinia herbicola antigenicity, and continued exploration of novel peptide-based bio simulants and research on a new viral simulant. Continued upgrading the data in the agent/simulant knowledge base technical information system and initiated the collection and quality assessment of toxicology data. Investigated physical properties and decontamination properties of B. mallei and baculovirus.

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BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	CB2

FY 2005 Accomplishments (Cont):

- 2035 Aerosol Technology - Continued investigations of approaches to advanced inlets for aerosol collection in high air speed conditions. Continued experimental studies of novel collectors, electrostatic collector, impeller, mini-slit, and other low power aerosol collection devices. Continued characterization of emerging collectors and collection technology. Upgraded existing chambers and wind tunnels. Continued evaluations of new and prototype chemical detectors using chemical simulant aerosols. Continued computational fluid dynamics (CFD) modeling for the windbreak approach of sampling from high speed flows. Efforts terminated in FY05 due to lack of JPEO requirements and to reprioritize funding for agent characterization and simulant development.
- 3275 Environmental Fate of Agents (DTO CB42) BCA#5/6/23/28/39 - Predictive Modeling - Evaluated Agent Fate secondary evaporation model versus the Vapor Liquid Solid Tracking (VLSTRACK) module and evaluated each with agent lab trials to determine accuracy of downwind vapor predictions. Tuned model/module and integrated into Joint Effects Model (JEM). Completed agent/inert substrate prediction model from lab-scaled wind tunnel data. Continued to work the scaling of agent vapor concentrations from laboratory to outdoor test conditions. Continued chemical hazard estimation method and risk assessment tool (CHEMRAT) update with new agent fate test data. Continued to update secondary evaporation model with new agent fate test data and incorporated into JEM.

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BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**CB2**

FY 2005 Accomplishments (Cont):

- 2800 Environmental Fate of Agents (DTO CB42) BCA#5/6/23/28/39 - Methodology Development - Determined degradation products of agents on surfaces of interest such as concrete. Examined the fate of nerve agents (VX, GD) and non-traditional agents (NTAs) on asphalt by nuclear magnetic resonance (NMR). Examined the fate of V analogs, NTAs and thickened agents on surfaces under different temperature and humidity conditions by HS-SPME. Determined sorption and fate of nerve agent (VX) on sand and clay soil. Determined sorption and fate of nerve agents (GD, VX) on assembled test soil.
- 7100 Environmental Fate of Agents (DTO CB42) BCA#5/6/23/28/39 - Lab/Large-Scale Wind Tunnel Studies - Continued surface residual agent testing to determine contamination levels. Completed surface evaporation tests of nerve agents (VX, GD) and blister agent (HD) on a non-porous substrate. Started surface evaporation testing of thickened CW agents on soil, asphalt and concrete.
- 500 Modeling and Simulation - Completed and transitioned agent/inert substrate prediction module to Joint Operational Effects Federation (JOEF) and JEM.
- 5500 Low Level Chemical Warfare Agent Exposure Effects and Countermeasures (DTO CB51) - Low Level Operational Toxicology Studies - Conducted cross-validation studies, based on a validated dosimetric for exposure route comparison that refine operational human health risk assessments for exposure to the nerve agents. Extended the useful range of prediction for inhalation exposures to nerve agent (GF) expected in various military response settings. Initiated nerve agent (VX) studies that extend time-effect predictive capability.
- 1200 Biological Agent Fate - Continued assessments of the persistence of biological warfare agents if released into operational environments.

Total 27878

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BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**CB2**

FY 2006 Planned Program:

- 5500 Agent Fate Environmental Fate of Agents (DTO CB42) BCA#5/6/23/28/39 - Continue Predictive Modeling, Methodology Development, Fundamental Laboratory Measurements and Outdoor Live Agent Testing of HD, VX and GD on operationally relevant surfaces. Use data to develop models and transition models to the Joint Effects Model (JEM).
- 967 Agent Fate Predictive Modeling in support of DTO CB42. BCA#5/6/23/28/39 - Complete HD and VX evaporation models from lab-scale wind tunnel data and validate model predictions in limited field trials. Complete liquid contact model.
- 2161 Agent Fate Methodology Development in support of DTO CB42 BCA#5/6/23/28/39 - Complete and publish reaction chemistry of HD, VX, and GD on concrete, asphalt, and sand.
- 6272 Agent Fate Fundamental Laboratory Measurements of the Environmental Fate of Chemical Agents on Surfaces in support of DTO CB42 BCA#5/6/23/28/39 - Complete laboratory surface evaporation tests of VX, limited tests of GD and HD, on operationally relevant surfaces.
- 2253 Agent Fate Lab/Large-Scale Wind Tunnel Studies in support of DTO CB42 - Complete surface evaporation tests of HD on operationally relevant surfaces in lab-scale and outdoor tests for model validation.
- 664 Agent Fate Biological Toxin Fate in Water Matrices - Continue to measure the persistence (viability) of biological warfare agents released into operational environments.

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BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**CB2**

FY 2006 Planned Program (Cont):

- 7760 Low Level Toxicology, Low Level Chemical Warfare Agent Exposure Effects and Countermeasures (DTO CB51) Low Level Operational Toxicology Studies - Conduct validation studies for predictive models that refine and extend the ability to extrapolate to human operational health risk from exposure to nerve agents. Complete GF exposure studies and extend time course and dose-response studies for VX non-threshold effects relevant to military response settings. Initiate studies for nerve agent GD that lead to a refined operational human health risk assessment. Continue and expand evaluations of inhalation toxicology for traditional agents to deliver science-based exposure standards for operational risk management decision tools.
- 400 Low Level Toxicology, Toxicokinetic and Toxicodynamic Modeling of Biological Agent - Initiate 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).
- 1347 Agent Characterization and Simulant Development - Continue applied research into NTA chemistry, characterizing synthetic pathways and NTA products, and developing NTA simulants.
- 2371 Agent Characterization and Simulant Development - Initiate simulant and methodology development projects to address requirements in programs of record, as aligned by the CBDP Test and Evaluation community.
- 267 Computational Chemistry - Independent assessment and evaluation of the Quantitative Structure Activity Relationship (QSAR) field.

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BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**CB2**

FY 2006 Planned Program (Cont):

- 907 Computational Chemistry - Quantum-Chemical Modeling of Chemical Warfare Agent (CWA)/adsorbent interaction - Initiate Quantum-Chemical modeling effort to compute the interaction of CWA simulants and real CWAs on oxide surfaces and other surfaces/materials of operational interest.
- 533 Computational Chemistry - in-silico Predictive Modeling Tools - Identify, validate and select a new suite of operationally suitable CWA simulants for Operational Test and Evaluation.
- 200 Computational Chemistry - Support the Biological Warfare module to the ARGUS data fusion capability. Develop a data mining tool to provide Indications and Warnings of enemy BW agent development.
- 250 Science Information Support - Provide support to OSD-CPP policy development efforts.

Total 31852

FY 2007 Planned Program:

- 2400 Agent Fate - Predictive Modeling for Thickened CWAs. Develop evaporation models of thickened HD and VX using data from lab-scale wind tunnel data and field trials. Transition models to the Joint Effects Model (JEM).
- 1333 Agent Fate - Fundamental Laboratory Measurements of Thickened CWAs on Surfaces. Kinetic studies of the fate of thickened VX and HD on operationally relevant surfaces.
- 3333 Agent Fate - Lab/Large-Scale Wind Tunnel Studies of Thickened CWAs. Refine protocols for laboratory wind tunnels and collect data on thickened HD and VX evaporation.

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BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**CB2**

FY 2007 Planned Program (Cont):

- 3500 Agent Fate - Environmental Fate of Non-traditional Agents. Initiate DTO CB68 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. Methodology development is a primary thrust of this first year of the DTO.
- 4333 Low Level Toxicology - Low Level Chemical Warfare Agent Exposure: Effects and Countermeasures (DTO CB51) - 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.
- 1333 Low Level Toxicology - Low Level Chemical Warfare Agent Exposure Effects and Countermeasures (DTO CB51) - Integration Studies. Deliver refined human health risk assessment for HD inhalation exposures suitable for incorporation into Operational Risk Management processes.
- 1333 Low Level Toxicology - Methodology Development in Support of DTO CB51. Continue development of technically demanding exposure and analytic methods for selected very low volatile chemical threat agents, such as non-traditional threat agents (NTA).
- 667 Low Level Toxicology - Toxicokinetic and Toxicodynamic Modeling of Biological Agent. Continue to develop 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).

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)	DATE February 2006

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	CB2

FY 2007 Planned Program (Cont):

- 7060 Low Level Toxicology - Chemical Warfare Agent Operational Exposure Hazard Assessment Research, NTA and Contact Toxicity. Initiate DTO CB69 research program 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 in previous year, expand and target studies that will directly lead to a human health risk assessment exposure standard.
- 1333 Agent Characterization and Simulant Development - Continue basic research into NTA chemistry, characterizing synthetic pathways and NTA products, and developing NTA simulants.
- 3333 Agent Characterization and Simulant Development - Continue simulant and methodology development projects to address requirements in programs of record, as aligned by the Test and Evaluation community. Initiate simulant correlation studies to define operational envelopes in which simulants may be used for Development Test and Operational Test.
- 1200 Computational Chemistry - Quantum-Chemical Modeling of CWA/adsorbent interaction - 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.
- 1333 Computational Chemistry - Transition COTS Quantitative Structure Activity Relationship (QSAR) toolsets to 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. Intent is to establish expertise and baseline against well-characterized substrates before moving toward human toxicology QSAR toolsets.

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DATE: **February 2006**

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**CB2**

FY 2007 Planned Program (Cont):

- 2667 Computational Chemistry - Continue Quantum-Chemical Modeling (QCM) tool development. Initiate 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.
- 931 Science Information Support - Support to OSD-CPP policy development efforts. Manpower, travel and conference costs for Management, Red Team, Blue Team and Senior Advisory Group support to the Joint community for Policy development ISO CB defense operations.
- 1333 Science Information Support - Data collection and generation to support policy development. Initiate scientific studies required by the Joint community to establish facts necessary for Policy development ISO CB defense operations.

Total 37422

	FY 2005	FY 2006	FY 2007
SBIR/STTR	0	1317	0

FY 2006 Planned Program:

- 1317 SBIR

Total 1317

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DATE: **February 2006**

BUDGET ACTIVITY: **RDT&E DEFENSE-WIDE/ BA2 - Applied Research**

PE NUMBER AND TITLE: **0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**

PROJECT: **CB2**

C. Other Program Funding Summary:

	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011	To Compl	Total Cost
CB3 CHEMICAL BIOLOGICAL DEFENSE (ATD)	87033	110219	78236	72496	75429	67855	56786	Cont	Cont
CP3 COUNTERPROLIFERATION SUPPORT (ATD)	4869	0	0	0	0	0	0	0	4869
TT3 TECHBASE TECHNOLOGY TRANSITION	0	11127	11087	7879	8340	8688	8627	Cont	Cont

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DATE: **February 2006**

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**TB2**

COST (In Thousands)		FY 2005 Actual	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	FY 2010 Estimate	FY 2011 Estimate	Cost to Complete	Total Cost
TB2	MEDICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)	42987	88779	145073	76474	54837	43864	41114	Continuing	Continuing

A. Mission Description and Budget Item Justification:

Project TB2 MEDICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH): This project funds applied research on the development of vaccines, therapeutic drugs, and diagnostic capabilities to provide an effective medical defense against validated biological threat agents including bacteria, toxins, and viruses. Innovative biotechnology approaches and advances will be incorporated to obtain medical systems designed to rapidly identify, diagnose, prevent, and treat disease due to exposure to biological threat agents. Categories for this project include Defense Technology Objectives (DTOs); science and technology programs in medical biological defense capability areas (Pretreatments, Diagnostics, Therapeutics and Emerging Threats); and directed research efforts, including the Chemical and Biological Defense Initiative (CBDI) fund. Categories under this project address the Joint Requirements Office (JRO) critical capability gaps identified in the baseline capability assessment performed in FY03. The specific critical capability gaps addressed are Gap #14 (Medical Prophylaxes - Lack of multi-valent vaccines), Gap #22 (Medical Therapeutics - Limited anti-viral/ toxin development), Gap #24 (Medical Therapeutics - Lack of FDA Approval for CBRN), Gap #35 (Diagnostics - Lack of portability), Gap #36 (Diagnostics - FDA Approval) and Gap #38 (Diagnostics - Reagent Verification).

B. Accomplishments/Planned Program

	FY 2005	FY 2006	FY 2007
Transformational Medical Technology Initiative	0	17484	108715

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DATE: **February 2006**

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**TB2**

FY 2006 Planned Program:

- 17484 Multiagent (Broad Spectrum) Medical Countermeasures - Pursue 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. Develop ex vivo cell-based model systems or minimize requirements for the study of medical countermeasure bioactivity, efficacy and safety. Develop a rapid re-sequencing technology using state of the art, commercially available microarrays.

Total 17484

FY 2007 Planned Program:

- 108715 Multiagent (Broad Spectrum) Medical Countermeasures - This effort is part of the Quadrennial Defense Review (QDR) "leading edge" investment to develop broad spectrum medical countermeasures against future genetically-engineered bio-terror threats, for which there are no current defenses. Develop massively parallel microfluidics techniques for analyzing protein and/or nucleic acid signatures at submicromolar levels in physiological fluids using nanotechnology advances to monitor pathogen/host pathogenesis pathway expression products. Continue to develop 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. Implement ex vivo cell-based model systems to replace animal models in the study of medical countermeasure bioactivity, efficacy and safety. Develop artificial cell/artificial tissue models for the testing of medical countermeasure bioactivity, efficacy and safety. Expand development of rapid re-sequencing applications.

Total 108715

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DATE: **February 2006**

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**TB2**

	FY 2005	FY 2006	FY 2007
Congressional Interest Items	20531	28031	0

FY 2005 Accomplishments:

- 3868 Alternative Delivery Methods for Recombinant Protein Vaccines - Developed countermeasures against bioterrorist attack by evaluating advanced vaccine delivery platforms that can be deployed rapidly and that allow self-vaccination.
- 1389 Biological Countermeasures (Rapid Antibody-Based Biological Countermeasures (RABBC)) - Generated vaccines and antibody-based biological weapon countermeasures to detect and treat known strains of native and weaponized bacterial pathogens.
- 992 BioTerNet Networking and Strain Tracking - Created a network that incorporates biological agent strain identification with tracking and enables quick dissemination of information to network participants.
- 992 Genetic Reassortment by Mismatched Repair-Enhanced Acute Biowarfare Therapy Program - Developed an enhanced, novel DNA shuffling technology able to generate large libraries of gene sequences faster and more efficiently than traditional technologies.
- 1785 Heat Shock Protein (HSP) Rapid Vaccine - Demonstrated an effective vaccine for smallpox using HSP.
- 992 Heteropolymer Anthrax Monoclonal Antibody - Developed Anthim, a heteropolymer monoclonal antibody, as a therapeutic to treat exposure to anthrax spores.

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BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**TB2**

FY 2005 Accomplishments (Cont):

- 1091 Multi-Purpose Biodefense Immunoarray - Developed a proteome microarray as a tool for flexible, rapid characterization of new and novel pathogens and expedited development of countermeasures.
- 2777 Novel Viral Biowarfare Agent ID and Treatment - Developed a novel approach to anti-viral therapeutics based on high-throughput screening of compounds against intermediates of the virus capsid assembly pathway.
- 2777 Vaccines and Therapeutics to Counter Biological Threats - Continued to explore efficacy of mucosally delivered vaccine candidates to bacterial and viral pathogens.
- 1389 Global Pathogen Portal - Aided the rapid detection, identification, and forensic attribution of high-priority biothreat pathogens by using analysis and visualization tools.
- 2479 Virginia Bioinformatics Institute - Built on previous work on the PathPort (Pathogen Portal) project by adding system enhancements, data curation and new system functionalities.

Total 20531

FY 2006 Planned Program:

- 991 Advanced Neutron Radiography.
- 3268 Alternative Delivery Methods for Recombinant Protein Vaccines - Continue development of countermeasures against bioterrorist attack by evaluating advanced vaccine delivery platforms that can be deployed rapidly and that allow self-vaccination.
- 2526 Biowarfare Diagnosis and Therapy via Mismatch Repair.

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BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**TB2**

FY 2006 Planned Program (Cont):

- 2526 Botulinum Neurotoxin Research (Only for Research on fluorescence resonance energy transfer assays and antagonists).
- 2476 Global Pathogen Portal (PathPort) - Continue to explore the rapid detection, identification, and forensic attribution of high-priority biothreat pathogens by using analysis and visualization tools.
- 991 Institute for Advanced Pharmaceutical Sciences.
- 1387 Multipurpose Biodefense Immunoarray - Continue development of a proteome microarray as a tool for flexible, rapid characterization of new and novel pathogens and expedited development of countermeasures.
- 3961 Novel Viral Biowarfare Agent ID and Treatment - Continue development of a novel approach to anti-viral therapeutics based on high-throughput screening of compounds against intermediates of the virus capsid assembly pathway.
- 991 Rapid Pathogen Amplification and Detection System (RPADS).
- 4952 Bug-to-Drug Program.
- 2971 Marburg Countermeasures.
- 991 Proteomics R&D improved Drugs and Diagnostics against BW.

Total 28031

	FY 2005	FY 2006	FY 2007
Diagnostics	3770	8186	10010

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BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**TB2**

FY 2005 Accomplishments:

- 2170 Diagnostic Technologies - Developed/evaluated new nucleic acid and immunoassays specific for different bacterial and viral targets in order to enhance current detection capabilities. Augmented toxin detection capabilities; designed tests to identify the presence of a biologically active toxin in a clinical sample. Directed research towards solving the technical problems associated with clinical sample preparation and rapid diagnostics; demonstrated equivalence of a manual kit and JBAIDS, Block I DNA extraction kit; resulted in a decreased sample requirement and eliminated the need for a large piece of deployable instrumentation. Tested DoD developed assays, reagents and sample preparation techniques and platforms in field studies. Demonstrated that recombinant antibodies for ricin and botulism significantly improved toxin detection capability in current gold standard assays. Initiated process to build a pathogen database for a DARPA transitioned broad range pathogen detection system capable of identifying genetically engineered strains. Initiated development of a proteomics-based microarray to detect the organism causing plague. Built a bioinformatics database correlating early biomarkers of infections caused by selected biological warfare agents.
- 1600 Diagnostic Technologies, Methodology to Facilitate Development of Biological Warfare Threat Agent Detection and Medical Diagnostic Systems (DTO CB56) - Began to elevate previously transitioned nucleic acid assays to test and evaluation standards established during FY04 beginning with assay(s) selected for JBAIDS, Block I.

Total 3770

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BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**TB2**

FY 2006 Planned Program:

- 6686 Diagnostic Technologies - Target a potential block improvement to Joint Biological Agent Identification and Diagnostic Systems (JBAIDS), Block I; design/initiate a multi-center comparison of automated extraction technologies versus the JBAIDS manual kit. Design multiplexed nucleic acid assays for the detection and identification of validated threat agents in clinical samples. Address gaps in and assess novel technologies for assay development. Continue to test DoD developed assays, reagents and sample preparation techniques and platforms in field studies; develop a more coordinated joint approach to performing field studies and providing useful feedback to assay developers. Evaluate newly developed assays targeting the presence of active toxin in a clinical sample; expand toxin diagnostics to support JBAIDS, Block II. Accelerate development of alternate sampling/extraction techniques to address JBAIDS, Block I gap in sample processing. Mature study assessing host response to immunization in biowarfare vaccine recipients. Expand evaluation of new chemistries for the identification of biological warfare agents to latest state-of-the-art methods. Mature recombinant DNA technologies for mass immunodiagnostic reagent production. Continue to build pathogen database for a DARPA transitioned broad range pathogen detection system capable of identifying genetically engineered strains. Further develop techniques to develop a proteomics microarray to detect plague infection. Identify gene sets corresponding to early biomarkers of infection caused by selected biological agents.
- 1500 Diagnostic Technologies, Methodology to Facilitate Development of Biological Warfare Threat Agent Detection and Medical Diagnostic Systems (DTO CB56) - Continue to elevate previously transitioned assays to test and evaluation with preference for assays selected for JBAIDS, Block I.

Total 8186

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BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**TB2**

FY 2007 Planned Program:

- 8410 Diagnostic Technologies - Expand design of multiplexed assays to include immunoassays. Continue to test DoD developed assays, reagents and sample preparation techniques and platforms in field studies. Field test confirmatory tests for toxins and continue to expand toxin diagnostics and to support JBAIDS, future diagnostic capability as new genomic data becomes available. Complete a multi-center comparison of automated extraction technologies versus the JBAIDS manual kit. Continue research directed at increasing sample concentration and extending sample viability prior to testing. Collate/analyze microarray data reflecting host response to immunization from biowarfare vaccine recipients. Continue to build a data base for a DARPA transitioned broad range pathogen detection system capable of identifying genetically engineered strains. Utilize proteomics data to design immunologic assays for biological pathogen detection. Collect data on host response to bacterial pathogens in order to develop gene sets. Continue to assess components of future comprehensive integrated diagnostic system suitable to both hand held and reference laboratory confirmatory testing. Investigate technologies capable of integrating nucleic acid and immunodiagnostic testing and initiate developmental testing in anticipation of support to JBAIDS, future diagnostic capability.
- 1600 Diagnostic Technologies, Methodology to Facilitate Development of Biological Warfare Threat Agent Detection and Medical Diagnostic Systems (DTO CB56) - Continue to elevate previously transitioned assays to test and evaluation with preference for assays selected for JBAIDS, Block I and potentially Block II.

Total 10010

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RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**TB2**

	FY 2005	FY 2006	FY 2007
Emerging Threats	1248	1679	1400

FY 2005 Accomplishments:

- 1248 Genetically Engineered Threats - Investigated structure of inhibitors of spore germination. Structure based rational design of biological warfare (BW) threat agent countermeasures using X-ray crystallographic techniques.

Total 1248

FY 2006 Planned Program:

- 526 Genetically Engineered Threats - Conduct evaluation of spore germination inhibitors and their effectiveness (research continuing into 2007 will be listed in the Therapeutics Area under Therapeutics for Bacterial Agents and Therapeutics for Viral Agents, as appropriate).

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BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**TB2**

FY 2006 Planned Program (Cont):

- 1153 Rapid Detection, Threat Assessment and Attribution of Genetically Engineered Biothreat Organisms Using Microarray-Based Resequencing Technologies (DTO CB64) - Provide for rapid, inexpensive, high-throughput, microarray-based DNA resequencing of biothreat agent genomes, whether they are naturally occurring, newly arising, or genetically engineered strains. Develop the capability to perform whole-genome sequencing in single laboratories with minimal space and personnel requirements at less than 1% of the current cost of existing, non-DOD industrial genome sequencing centers. Enable immediate definitive identification of the organism and provide specific data on the presence of any engineered elements. Develop and implement collection procedures and expand biothreat agent strain collection. Demonstrate and evaluate two high-density microarray systems.

Total 1679

FY 2007 Planned Program:

- 1400 Rapid Detection, Threat Assessment and Attribution of Genetically Engineered Biothreat Organisms Using Microarray-Based Resequencing Technologies (DTO CB64) - Demonstrate greater than 3-fold scale up of high-throughput experimental protocols and systems for rapid microarray-based resequencing. Resequence 10 B. anthracis and 10 Y. pestis group genomes; release data to other relevant DOD projects. Expand biothreat agent strain collection. Evaluate microarray feature size reduction/increased density on two platforms.

Total 1400

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RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**TB2**

	FY 2005	FY 2006	FY 2007
Pretreatments	6662	15585	13843

FY 2005 Accomplishments:

- 500 Multiagent Vaccines, Western and Eastern Equine Encephalitis (WEE/EEE) Vaccine Constructs for a Combined Equine Encephalitis Vaccine (DTO CB58) - Continued to analyze mutants with various engineered attenuating mutations to determine their suitability for use as vaccine platforms. Enhanced studies to establish an eastern equine encephalitis (EEE) virus non-human primate efficacy model.
- 700 Multiagent Vaccines, Vaccine Technologies for Protection Against Filovirus (Marburg and Ebola Viruses) Exposure (DTO CB60) - Incorporated antigen targets from earlier studies to improve vaccine candidates as determined from characterization studies and concurrent testing.

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RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**TB2**

FY 2005 Accomplishments (Cont):

- 5462 Vaccine Research Support - Continued to develop lead vaccine candidates against plague (F1-V fusion antigen vaccine) and ricin. Evaluated the role of capsule in the development of a generation-after-next anthrax vaccine. Investigated anthrax spore interactions with host cells and characterization of diverse B. anthracis strains for vaccine resistance. Continued studies on the ability of functional domains of botulinum neurotoxins (BoNT) to elicit protective immunity in animal models. Accelerated studies to increase immunogenicity of existing recombinant BoNT heavy chains (Hc) subunit vaccine candidates via adjuvants and/or method of delivery. Developed in-process and release assays for recombinant BoNT Hc vaccine candidates. Tested recombinant ricin vaccine (rRTA) candidate stability. Developed surrogate endpoints of clinical efficacy for higher animal species in ricin vaccine adjuvant studies. Tested novel adjuvants with lead ricin vaccine candidate. Determined stability of Staphylococcal Enterotoxin (SE) vaccine candidates. Tested oligonucleotide CpG as an adjuvant with live attenuated alphavirus vaccine candidates. Completed studies on correlates of immunity that protect against disease from filoviruses and alphaviruses. Evaluated the use of Virus-Like Particles (VLP) as antigen for vaccines for filoviruses. Began evaluation of a VEE replicon-based Marburg virus vaccine candidate.

Total 6662

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RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**TB2**

FY 2006 Planned Program:

- 500 Multiagent Vaccines, Western and Eastern Equine Encephalitis (WEE/EEE) Vaccine Constructs for a Combined Equine Encephalitis Vaccine (DTO CB58) - Evaluate new EEE vaccine approaches in animal models in combination with WEE vaccine construct(s) and already transitioned VEE vaccine candidate V3526 or alternate VEE vaccine candidates made in the DNA- or replicon-based vaccine platforms. Initiate duration of immunity studies with lead candidates for each platform, comparing the individual constructs and trivalent formulations.
- 2500 Multiagent Vaccines, Multi-agent (molecular) Vaccines for Bio-Warfare Agents (DTO CB65) - Explore both molecular and protein-based trivalent vaccine platforms. Identify third pathogen to be targeted as the third component of the trivalent vaccine and initiate candidate antigen incorporation into a candidate vaccine construct for evaluation. Develop the optimal DNA backbone in combination with adjuvant formulation. Evaluate multi-epitope DNA vaccine constructs. Explore the use of alternative delivery strategies for optimizing the efficacy of genetic immunization. Focus development on DNA vector delivery systems that stimulate protective immunity following minimal dosing.

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BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**TB2**

FY 2006 Planned Program (Cont):

- 3600 Multiagent Vaccines - (Formerly under Animal Models and Resuscitative Intervention) - Develop definitive non-human primate model to evaluate the efficacy of separate and combined VEE/WEE/EEE vaccine candidates (Venezuelan, Western, and Eastern equine encephalitis virus, respectively). Analyze additional WEE/EEE mutants with various engineered attenuating mutations. 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. Evaluate target antigens for Ebola virus vaccine development. Explore additional use of Virus Like Particles (VLP) or other viral constructs as antigen delivery platforms for filovirus vaccine development. Continue the evaluation of a VEE replicon-based Marburg virus vaccine platform. Start down-selection phase of the various filovirus vaccine candidate constructs (platforms) and evaluate alternative forms of delivery for comparative evaluation of vaccine efficacy.

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RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**TB2**

FY 2006 Planned Program (Cont):

- 5985 Vaccine Research Support - Initiate the evaluation of intracellular pathogen candidate antigens using animal model systems including the use of alternative delivery platforms. Begin immunogenicity studies for generic Bacillus vaccine target antigens. Evaluate B and T cell epitope mapping of lead protective antigen candidates. Continue to evaluate novel antigen targets for next generation anthrax and plague vaccine development. Evaluate incorporation of recombinant lethal factor and edema factor from B. anthracis into an anthrax vaccine candidate for a multiagent vaccine approach. Examine in vivo antigen expression/recognition in non-human primates (NHPs). Evaluate the immunogenicity of intact catalytic and translocation domains of botulinum neurotoxins (BoNT). Continue developing in-process and release assays for recombinant BoNT Hc vaccine candidates. Continue recombinant ricin vaccine candidate stability testing. Continue to develop surrogate endpoints of clinical efficacy for higher animal species in ricin vaccine adjuvant studies. Clone/express proposed Staphylococcal Enterotoxin A (SEA)/Staphylococcal Enterotoxin B (SEB) structural determinants; determine stability of immunogens; raise neutralizing antibodies against immunogens and test for cross-reactivity among SE serotypes using in vitro systems.
- 3000 Vaccine Technology Development - (formerly under Resuscitative Intervention) Evaluate a recombinant protein-based trivalent vaccine (anthrax/plague/ricin) based on prototype anthrax/plague vaccine studies. Evaluate additional trivalent vaccine candidates that combine protection against anthrax and plague, as well as one additional target biothreat agent (e.g. Botulinum neurotoxin, Staphylococcus enterotoxin A/B, or an intracellular pathogen) using currently identified protective antigens. Test 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). Accelerate the development and design of generic gene-based vaccines targeting common target sequences in pathogens.

Total 15585

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RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**TB2**

FY 2007 Planned Program:

- 500 Multiagent Vaccines, Western and Eastern Equine Encephalitis (WEE/EEE) Vaccine Constructs for a Combined Equine Encephalitis Vaccine (DTO CB58) - Complete evaluation of live, site-directed mutagenized, attenuated viral vaccine. Perform final dose ranging studies in non-human primates (NHP) for efficacy of multiagent viral vaccine candidates. Evaluate a combined Venezuelan, Eastern, and Western Equine Encephalitis (VEE, EEE, and WEE, respectively) vaccine by identifying and characterizing WEE and EEE vaccine constructs that would be appropriate to combine into a single vaccine with the already transitioned VEE vaccine candidate V3526, or with alternative VEE vaccine candidates made in the DNA- or replicon-based vaccine platforms.
- 2500 Multiagent Vaccines - Multi-agent (molecular) Vaccines for Bio-Warfare Agents (DTO CB65) - Express the select bio-threat agent target from the DNA vector delivery system and assess immunogenicity and protective efficacy (injected and aerosol challenge) in animal models alone and in combination with the anthrax and plague elements. 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.

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RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**TB2**

FY 2007 Planned Program (Cont):

- 4119 Multiagent Vaccines - (formerly under Animal Models and Resuscitative Intervention) Conduct dose and antigen interference studies for the combined VEE/WEE/EEE (protein) vaccine in the definitive animal model. Concentrate continued filovirus vaccine development on down-selected vaccine delivery platform(s) based on assessment of most efficacious vaccine candidate. Continue assessment of candidate anthrax/plague multi-agent vaccines in animal models. Continue development and refinement of in vitro correlates of immunity. 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. Refine applied research to define correlates of immunity that protect against disease from filoviruses and alphaviruses. Continue to conduct studies of selected recombinant Ebola vaccine candidates. Finalize the evaluation of a VEE replicon-based Marburg virus vaccine candidate.
- 3224 Vaccine Research Support - Complete efficacy studies of ricin vaccine candidate through animal challenge models, including non-human primate studies. Continue the exploration of additional intracellular pathogen target antigens using animal model systems including the use of alternative delivery platforms. Accelerate B and T cell epitope mapping of lead protective antigen candidates. Test next-generation Staphylococcal Enterotoxin A/Staphylococcal Enterotoxin B (SEA/SEB) immunogens as vaccine candidates to protect against multiple SE serotypes in vivo. Complete stability and immunogenicity of SEB toxin vaccine in support of clinical trial. Continue studies on the immunogenicity of intact functional domains of botulinum neurotoxins (BoNT). Complete developing the in-process and release assays for recombinant BoNT Hc vaccine candidates. Evaluate enhanced next generation anthrax and/or plague vaccine candidates.

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RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**TB2**

FY 2007 Planned Program (Cont):

- 3500 Vaccine Technology Development - Continue to explore novel genetic immunization platforms toward the development of a multiagent anthrax-plague vaccine strategy and evaluate through animal immunogenicity studies. Begin 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. Evaluate vaccine performance requirements (route, dose, number of doses) in animal models. Determine adjuvant formulations/systems that enhance the efficacy of molecular vaccines in animal models. Expand alternative immunization platforms such as VLP, VEE replicons and adenoviral constructs for efficacy against selected biothreat pathogens and/or toxins. Continue to evaluate candidate vaccines in conjunction with oligonucleotide-based enhancement of the immune response. 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. Assess intracellular pathogen common target antigens for cross-reactivity/vaccination potential. Continue assessment of user-friendly vaccination modalities which confer rapid protection following minimal dosing.

Total 13843

	FY 2005	FY 2006	FY 2007
Therapeutics	10776	16959	11105

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RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**TB2**

FY 2005 Accomplishments:

- 1565 Therapeutics, Bacterial - Performed therapeutic efficacy studies in non-human primate models using hollow fiber bridging data. Studied on selected FDA-licensed antimicrobial compounds to support consideration for changing label indications for use against category A and B Biological Warfare (BW) threat agents.
- 2735 Therapeutics, Toxin - Assessed surrogate endpoints of human clinical efficacy for Staphylococcal Enterotoxin (SE) therapeutics. Identified two caspase inhibitors to counteract toxic effects of SEs, tested and evaluated their therapeutic efficacy in murine Lipopoly Saccharide (LPS)-potentiated model. Produced homozygous transgenic mice expressing high levels of human Major Histo-compatibility Complex (MHC) class II/human CD4 receptors. Found that aerosolized Staphylococcal Enterotoxin B (SEB) could induce lung lesions in the transgenic mice, similar to SEB lesions induced in non-human primates.
- 576 Therapeutics, Viral - Tested and evaluated therapeutic action of pharmacological compounds provided by industry in mouse and non-human primate models of filovirus infection. Developed methods for whole genome sequencing and completed the sequence of whole genome of monkeypox virus Katako Kombe and discovered new sequences to be used to design new therapeutic targets.

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)	DATE February 2006

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	TB2

FY 2005 Accomplishments (Cont):

- 2400 Therapeutics, Therapy for Smallpox and Other Pathogenic Orthopox Viruses (DTO CB54) - Completed studies to evaluate drug efficacy of intravenous (IV) cidofovir in primate models that support the Food and Drug Administration (FDA) Animal Efficacy Rule. Evaluated activity in monkeypox primate animal model. Evaluated an oral prodrug of cidofovir to determine if it is a replacement for IV cidofovir. Identified new molecular targets and developed assays specific for those targets. Evaluated antiviral activity of collections of compounds to identify lead structures for development into antiviral drugs with emphasis on compounds acting through a different mechanism than inhibition of viral DNA polymerase. Identified and tested leading antivirals in appropriate animal models. Identified potential mediators of shock or toxemia and determined the basis for the pathogenesis of shock or toxemia in animal models. Performed a sequential sacrifice of variola in non-human primates (NHP) and evaluated a monkeypox virus containing the green fluorescent protein in NHP for use in companion sequential sacrifice study.
- 2500 Therapeutics, Toxin, Therapeutic Strategies for Botulinum Neurotoxins (DTO CB59) - Developed recombinant human antibodies as passive immunotherapeutics against toxin A subtypes A1 and A2. Examined structural analogs of active-site inhibitors identified by high-throughput screening. Identified candidate Botulinum Neurotoxin (BoNT) receptor antagonists as therapeutic candidates. Established a central database and compound repository. Initiated ex vivo evaluation of lead compounds in model systems for therapeutic efficacy. Standardized in vivo concept model systems for assessment of therapeutic efficacy and surrogate endpoints of human clinical efficacy for botulinum.

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)	DATE February 2006

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**TB2**

FY 2005 Accomplishments (Cont):

- 1000 Therapeutics, Viral, Therapeutic Strategies for Treating Filovirus (Marburg and Ebola Viruses) Infection (DTO CB63) - Evaluated preliminary effectiveness and identified possible mechanisms of protection by previously uncharacterized monoclonal antibodies specific for Marburg (TB2) and Ebola (TB3) viruses. Performed a study in macaques challenged with Marburg virus (strain Ci67) to characterize the pathogenesis of Marburg virus in support of the FDA two animal efficacy rule.

Total 10776

FY 2006 Planned Program:

- 2220 Therapeutics, Bacterial - Test Antibacterial cytokine-based therapeutic candidates. Test CpG motifs (stimulators of immune response) in conjunction with antibiotics for plague therapy in an animal model. Continue to advance the assessment of selected compounds for safety and efficacy against multiple bacterial threat agents in non-human primates. Enhance aerobiology capabilities and animal model development to facilitate bacterial therapeutics research.
- 3813 Therapeutics, Toxin - Develop formulations or prodrugs to overcome problems with metabolism, bioavailability or pharmacokinetics of compounds with otherwise acceptable antiviral profiles of new compounds. Test efficacy of combinations of monoclonal antibodies against multiple toxin serotypes in cell-based systems. Continue ongoing proof-of-concept studies with lead toxin therapeutics in vivo using qualified surrogate endpoints of human clinical efficacy.

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)	DATE February 2006

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**TB2**

FY 2006 Planned Program (Cont):

- 2219 Therapeutics, Viral - Standardize leading antivirals in appropriate animal models. Develop and execute initial steps in plan for licensure and manufacturing with lead compounds, leading up to milestone approval and transition. Develop additional advanced applied resuscitative technologies that integrate established and emerging viral therapeutic modalities into suitable candidate therapies in humans.
- 1800 Therapeutics, Therapy for Smallpox and Other Pathogenic Orthopox Viruses (DTO CB54) - Conduct initial evaluation in pock lesion variola primate model at the Centers for Disease Control and Prevention. Evaluate oral cidofovir prodrug against monkeypox in primate model. Conduct initial studies to determine drug efficacy. Evaluate minimal and sufficient viral therapeutic requirements such as dose, route, and area under the curve. Perform appropriate testing in nonhuman primates for FDA licensure consideration under the FDA Animal Efficacy Rule.
- 1000 Therapeutics, Toxin, Therapeutic Strategies for Botulinum Neurotoxins (DTO CB59) - Develop lead mixtures of human antibodies against Botulinum Neurotoxin (BoNT) as passive immunotherapeutics in vivo. Complete 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. Generate information from research and use to develop a strategy, in concert with the advanced developer, for development of BoNT therapeutic candidates. Generate information from research and use to prepare a technology development plan for non-clinical studies of optimum therapeutic candidates/treatment modalities.

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)

DATE: **February 2006**

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**TB2**

FY 2006 Planned Program (Cont):

- 500 Therapeutics, Viral, Therapeutic Strategies for Treating Filovirus (Marburg and Ebola Viruses) Infection (DTO CB63) - Conclude data to select anti-Marburg monoclonal antibodies for molecular reengineering and primate testing. Begin shift from discovery of protein targets for Marburg virus therapy to testing of compounds to inhibit protein-protein interactions. Expand characterization of the role of neutrophils in innate and adaptive immunity to Marburg virus, focusing on cellular pathways possibly common to many viruses. Complete analysis of studies performed to evaluate the utility of recombinant nematode anticoagulant protein c2 (rNAPc2) against Marburg hemorrhagic fever in nonhuman primates.
- 5407 Resuscitative Intervention - Develop 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. Develop combined injury animal model (trauma and BW/CW agent) for a vesicating agent. Identify early markers via genomic or proteomic analysis, and physiologic status of interactive effects of combined injury in appropriate animal model. Initiate studies with Defense Advanced Research Projects Agency (DARPA) funded collaborators on ex vivo and in silico methods to model immune system function. Conduct initial evaluation of the pock lesion/variola primate model at the Centers for Disease Control and evaluate the oral prodrug Cidofovir for efficacy. Expand characterization of the monkeypox vs. primate-small pox model to prepare data packages for oral prodrug licensure.

Total 16959

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)	DATE February 2006

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**TB2**

FY 2007 Planned Program:

- 4131 Therapeutics, Bacterial - Refine conceptual development and execute in vivo testing of novel broad-based innate immunity modulator therapeutic approaches against naturally occurring and genetically engineered category A bacterial pathogens, such as plague/anthrax. Continue investigation of specific licensed and investigational antibacterial products for use against these threat agents.
- 3555 Therapeutics, Toxin - Complete ongoing proof-of-concept studies with lead toxin therapeutics in vivo using qualified surrogate endpoints of human clinical efficacy. Develop and execute initial steps in plan for licensure and manufacturing with lead compounds, leading up to milestone approval and transition.
- 1210 Therapeutics, Viral - Screen novel antiviral compounds, optimize leading antivirals in appropriate animal models. Evaluate specific viral therapeutic requirements such as dose, route, and area under the curve. Explore adjuvant immunomodulatory and host-response therapeutic interventions in in-vitro and in-vivo systems.
- 1800 Therapeutics, Therapy for Smallpox and Other Pathogenic Orthopox Viruses (DTO CB54) - Therapy for Smallpox and Other Pathogenic Orthopox Viruses - Development of the oral prodrug for therapy of smallpox, advanced efficacy studies in the preparation of investigational new drug (IND) submission package for the FDA.
- 409 Therapeutics, Therapy for Ebola and Marburg Virus Infections (DTO CB63) - Develop and characterize therapeutic technologies against the Ebola virus and Marburg virus. Technologies include antisense oligonucleotides, recombinant human monoclonal antibodies, small interfering RNAs, small molecules, and therapeutic vaccines. Improve existing animal models for filoviral hemorrhagic fever. Begin stringent comparative efficacy studies to identify "best performing strategies."

Total 11105

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)

DATE: **February 2006**

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**TB2**

	FY 2005	FY 2006	FY 2007
SBIR/STTR	0	855	0

FY 2006 Planned Program:

- 855 SBIR

Total 855

C. Other Program Funding Summary:

	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011	To Compl	Total Cost
TB3 MEDICAL BIOLOGICAL DEFENSE (ATD)	67899	88830	96736	143039	200722	229218	131723	Cont	Cont

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CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)

DATE: **February 2006**

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**TC2**

COST (In Thousands)		FY 2005 Actual	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	FY 2010 Estimate	FY 2011 Estimate	Cost to Complete	Total Cost
TC2	MEDICAL CHEMICAL DEFENSE (APPLIED RESEARCH)	24426	23657	30682	38927	41418	40598	39136	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 prevention of chemical casualties. Categories under this project address the Joint Requirements Office (JRO) critical capability gaps identified in the baseline capability assessment performed in FY03. The specific critical capability gaps addressed are Gap #15 (Medical Prophylaxes - Lack of prophylaxes for chemical warfare agents), Gap #24 (Medical Therapeutics - Lack of FDA Approval for CBRN), Gap #35 (Diagnostics - Lack of portability), and Gap #38 (Diagnostics - Reagent Verification).

B. Accomplishments/Planned Program

	FY 2005	FY 2006	FY 2007
Congressional Interest Items	7687	2526	0

FY 2005 Accomplishments:

- 992 Neurotoxin Mitigation Research - Investigated the wide array of circulating serum proteins that may bind organophosphate poisons in a mouse model, to identify potential new target proteins to serve as less expensive bioscavengers than the highly expensive compound now in development. Several new potential compounds were identified for future consideration as prophylactic and therapeutic agents.

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)

DATE: **February 2006**

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**TC2**

FY 2005 Accomplishments (Cont):

- 6695 Mustard Gas Antidote Research STIMAL - Continued studies on mustard inhalation models to evaluate efficacy of anti-oxidant liposomes in protection of the respiratory tree. Evaluated additional pharmacogenically-based drugs and complement blockade compounds for vesicant agent therapies.

Total 7687

FY 2006 Planned Program:

- 2526 Mustard Gas Antidote.

Total 2526

	FY 2005	FY 2006	FY 2007
Diagnostics	738	1757	1486

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)

DATE: **February 2006**

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**TC2**

FY 2005 Accomplishments:

- 738 Diagnostic Technologies - Conducted applied research aimed at improving detection methods in clinical samples for metabolites, adducts and/or relevant biomarkers resulting from chemical warfare exposure. Applied assessment of a non-invasive immunodiagnostic test detecting sulfur mustard skin exposure before the onset of vesication to the proven dermatological practice of skin tape stripping. Compared alternate sample/collection technologies; initiated research examining gas chromatography mass spectrometry (GC-MS)/solid phase micro-extraction as a simple and quick screen to verify exposure to Chemical Warfare Agent (CWA) using simulated urine. Completed laboratory validation of a DoD developed whole blood cholinesterase assay for organophosphate exposure and accumulated data comparing this method to classical standard techniques.

Total 738

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)

DATE: **February 2006**

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**TC2**

FY 2006 Planned Program:

- 608 Diagnostic Technologies - Continue applied research experiments aimed at improving detection methods in clinical samples for metabolites, adducts and/or relevant biomarkers resulting from chemical warfare exposure. Finalize assessment of a noninvasive immunodiagnostic test detecting sulfur mustard skin exposure before the onset of vesication to the proven dermatological practice of skin tape stripping. Further develop alternate sample collection/extraction technology(s); complete research examining gas chromatography mass spectrometry (GC-MS)/solid phase micro-extraction as a simple and quick screening method to verify exposure to CWA in simulated urine. Using the DoD developed whole blood cholinesterase assay for organophosphate exposure, assess a healthy population with no known exposure for known test marker inhibitors and atypical marker phenotypes. Establish baseline studies for assay development for additional selected chemical agents to include preparation of standard curves, linearity and limits of detection/quantitation studies.
- 1149 Animal Models - Conduct animal studies for detecting biomarkers of CW agent exposure in biological samples; explore longevity of biomarkers for the sulfur mustard blood protein adduct assay and fluoride reactivation assay by utilizing/interfacing with ongoing relevant animal exposure models. Assess ability of immunohistological and specialized protein detection techniques to detect sulfur mustard-induced skin changes in relevant animal models.

Total 1757

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)

DATE: **February 2006**

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**TC2**

FY 2007 Planned Program:

- 486 Diagnostic Technologies - Accelerate applied research experiments aimed at improving detection methods in clinical samples for metabolites, adducts and/or relevant biomarkers resulting from chemical warfare exposure. Continue to adapt the DoD developed whole blood cholinesterase assay for organophosphate exposure to automation/high throughput; conduct experiments examining changes in marker profiles after exposure to low level amounts of nerve agents and organophosphate pesticides; 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.
- 1000 Animal Models - Continue to conduct animal studies for detecting biomarkers of CW agent exposure in biological samples; complete studies exploring the longevity of biomarkers. Initiate metabolic profile (metabonomic) studies by examining blood from agent exposed guinea pigs and assess feasibility as a potential diagnostic technique.

Total 1486

	FY 2005	FY 2006	FY 2007
Emerging Threats	6192	2959	0

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)	DATE February 2006

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**TC2**

FY 2005 Accomplishments:

- 2605 Chemical Warfare Agent Defense, Low Level CW agents Exposure: Effects and Countermeasures (DTO CB51) - Completed assessments of the short-term effects of VX nerve agent on higher order behavioral tasks in non-human primates following a range of low-dose exposures for varying durations to improve estimates of impact on human operational readiness. Completed initial species and route integration studies that provide a basis for more accurate extension of results to human military operational risk assessment.
- 3587 Nerve Agent Defense, Non-Traditional Nerve Agent Medical Countermeasures (DTO CB57) - Evaluated the effectiveness of anticonvulsants against seizures produced by NTAs, in vivo (inside the organism) persistence of NTAs, and current medical countermeasures against NTAs. Conducted evaluation of respiratory dynamics and lung biochemistry.

Total 6192

FY 2006 Planned Program:

- 2959 Non-Traditional Agent Medical Countermeasures - Compare non-traditional and conventional nerve agents for induction of neurochemical changes. Evaluate countermeasures against non traditional cytokine agents (e.g. effect on inflammation reaction and bronchoconstriction). Identify target molecules for intervention against peptide NTAs and additional convulsant agents. Initiate development of animal model for peptide NTAs.

Total 2959

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)

DATE: **February 2006**

BUDGET ACTIVITY: **RDT&E DEFENSE-WIDE/ BA2 - Applied Research**

PE NUMBER AND TITLE: **0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**

PROJECT: **TC2**

	FY 2005	FY 2006	FY 2007
Pretreatments	3504	4931	8933

FY 2005 Accomplishments:

- 482 Chemical Warfare Agent Defense, Cyanide Medical Countermeasures - Screened anti-cyanide compounds for efficacy. This project area was terminated due to budgetary considerations and lack of research progress.
- 3022 Nerve Agent, Bioscavengers - Completed development of transgenic animals that can produce sufficient amounts of recombinant enzyme scavengers for clinical trials. Completed feasibility testing of vector/gene combinations to validate the concept of gene therapy for bioscavengers. Continued pretreatment intervention studies of vectors to deliver bioscavenger genes.

Total 3504

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)

DATE: **February 2006**

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**TC2**

FY 2006 Planned Program:

- 4931 Nerve Agent, Bioscavengers - Continue pretreatment intervention studies of vectors to deliver bioscavenger genes. Develop genetic knock-out murine animal models for catalytic bioscavenger studies (Block II). Evaluate different delivery systems for administration of recombinant and/or catalytic bioscavengers in vivo (Block II). Develop procedures and systems for large scale purification of recombinant bioscavengers (Block II). Expand the evaluation of human protein catalytic bioscavengers. Evaluate 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.

Total 4931

FY 2007 Planned Program:

- 8933 Nerve Agent, Bioscavengers - Evaluate recombinant methods and expression systems for larger scale production and purification of recombinant and catalytic bioscavenger proteins (Block II). Perform initial evaluation studies of catalytic bioscavenger molecules in genetic knock-out mice. Continue to develop knock-out murine models for evaluation of recombinant and catalytic bioscavenger molecules. Accelerate the determination of 3-D structure of human bioscavenger proteins. Determine efficacy of catalytic bioscavenger molecules against all types of nerve agents using inhalation toxicokinetics. Continue development of peptide drugs as potential bioscavenger molecules. Identify new native/recombinant catalytic bioscavengers molecules. Develop methods to improve/modify the catalytic efficiency of selected bioscavenger molecules. Develop more efficient delivery formulation. Develop methods(s) to significantly reduce or eliminate the inherent immunogenicity of recombinant bioscavenger molecules.

Total 8933

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)

DATE: **February 2006**

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**TC2**

	FY 2005	FY 2006	FY 2007
Therapeutics	6305	11255	20263

FY 2005 Accomplishments:

- 964 Nerve Agent Defense, Improved Oxime (DTO CB48) - Completed assay development and stability studies. Completed the identification and characterization of a surrogate marker for efficacy of candidate oxime(s) for use against traditional nerve agents and Non Traditional Agents.
- 579 Nerve Agent Defense, Nerve Agent Anticonvulsants - Evaluated efficacy of combinations of midazolam with selected anticholinergic compounds against nerve agent seizures in rodent (guinea pig) and relevant animal models. Developed analytical method to detect therapeutic levels of the anticholinger compound scopolamine in blood and tissue. Continued to develop a method to directly assay atropine levels in blood. Assessed application of emerging therapy for organophosphate insecticide poisoning to nerve agent exposure. Continued testing of drug combinations against seizures and lethality produced by all current threat agents.
- 434 Nerve Agent Defense, Neuroprotection - Tested putative neuroprotectants in animal model. Investigated potential markers for neuroprotectant effects (e.g., Electroencephalography (EEG) power spectrum, pulse oximetry, neuroimaging). Developed and validated a neurobehavioral model for change in ability to carry out complex behavior after recovery from nerve agent toxicity.

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)	DATE February 2006

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**TC2**

FY 2005 Accomplishments (Cont):

- 1263 Vesicant Agent Defense, Vesicant Medical Countermeasures - Collated available industrial documentation. Strengthened technology transfer mechanisms. Developed in vivo/in vitro models. Procured compounds for screening modules. Initiated screening procedures. Prioritized screened compounds. Selected compounds for further safety and efficacy evaluation.
- 1929 Vesicant Agent Defense, Cutaneous Therapeutics - Completed development of a superficial dermal vesicant injury model in weanling pigs. Began development of a sulfur mustard cutaneous wound healing model using African green monkeys for advanced efficacy studies of promising treatment regimens. Completed development of an in vitro wound healing model using human epidermal keratinocytes to screen pharmacological interventions for the effective treatment of cutaneous sulfur mustard injuries. Began development of an in vitro wound healing model using porcine epidermal keratinocytes for use as a bridge between in vitro studies using human epidermal keratinocytes and in vivo studies using weanling pigs. Evaluated additional commercially available wound healing products for their efficacy in promoting improved healing of superficial dermal sulfur mustard injuries using a validated weanling pig model.
- 482 Chemical Warfare Agent Defense, Inhalational Therapeutics - Established in-house and collaborative research programs to investigate therapy for multiple agent exposure.
- 654 Chemical Warfare Agent Defense, Skin and Wound Decontamination - Completed comparison of the efficacy of Reactive Skin Decontamination Lotion (RSDL) versus the Gordon polyurethane sponge against challenge by nerve agent GD. Initiated similar studies with challenge by nerve agents VX and HD. Initiated the efficacy evaluation of the Gordon polyurethane sponge with added nucleophiles challenged by nerve agent HD. Determined the efficacy of the M291 Skin Decontamination Kit challenge by VX.

Total 6305

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)

DATE: **February 2006**

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**TC2**

FY 2006 Planned Program:

- 1188 Nerve Agent Defense, Improved Oxime - Utilize current and novel approaches to conduct molecular modeling and structure activity relationship (SAR) studies of oxime reactivation of nerve agent inhibited acetylcholinesterase (AChE) with the goal of understanding how different oximes interact with human and non-human AChE inhibited by different nerve agents.
- 2000 Nerve Agent Defense, Nerve Agent Anticonvulsants - Evaluate the efficacy of new novel anticonvulsant compounds against nerve agent-induced seizures using in vivo models. Determine efficacy of midazolam, and/or anticholinergic compounds against nerve agent-induced seizures and lethality. Continue to assess pharmacokinetics of lead anticonvulsants against organophosphates.
- 2670 Nerve Agent Defense, Neuroprotection - Develop and refine screening protocol for candidate down-select. Refine animal models and validate small and large animal neurobehavioral test batteries. Investigate long-term neuroprotective strategies, including the role of steroid hormones.
- 1600 Vesicant Agent Defense, Vesicant Medical Countermeasures - Refine in vitro tissue and in vivo animal models. Study multi-photon imaging as a therapeutic modality.

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)	DATE February 2006

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**TC2**

FY 2006 Planned Program (Cont):

- 2000 Vesicant Agent Defense, Cutaneous Therapeutics - Complete development of advanced animal injury models, including (1) a sulfur mustard wound healing model using African green monkeys 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. Use 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. Assess instrumentation to evaluate depth of cutaneous vesicant injury, for use as a prognostic indicator.
- 500 Chemical Warfare Agent Defense, Inhalation Therapeutics - Refine and integrate animal models with screening protocols for therapeutics studies, including the novel use of macrolide antibiotics to protect against lung injury.
- 700 Chemical Warfare Agent Defense, Skin and Wound Decontamination - Evaluate the effectiveness of new commercial skin decontamination formulations to agent challenge as a function of time. Continue development of a decontaminating wound product(s) that can be applied before or after exposure, and can be used in and around the eyes and wounds.
- 597 Animal Models - Develop a non-human primate percutaneous testing model for chemical warfare agent exposure. Initiate assessment of 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. Evaluate the African green monkey, and the Marmoset, as alternate non-human primate models by: determining the toxicity of nerve agents sarin, tabun, cyclosarin, VX, VR, and selected non-traditional agents (NTAs); determining the efficacy of currently licensed medical countermeasures against this panel of chemical warfare agents.

Total 11255

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)	DATE February 2006

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**TC2**

FY 2007 Planned Program:

- 9045 Therapeutics, Neurologic - Use current and novel approaches to explore potential broad spectrum reactivators to nerve agent challenge. Synthesize prospective candidate reactivators and conduct reactivation studies to determine efficacy and toxicity in vitro/in vivo. Determine the optimal therapy for effective treatment of seizures under all potential field conditions (immediate or delayed treatment). Expand evaluation of putative neuroprotectants that have demonstrated effectiveness in neuronal rescue particularly Food and Drug Administration (FDA)-approved products which may have additional neuroprotective activity.
- 4421 Therapeutics, Cutaneous and Ocular - Complete efforts to develop in vitro tissue assays and design screening protocol(s) to down-select candidate compounds. Initiate protocol(s) and screen new/novel compounds using in vitro/in vivo techniques. Refine therapeutic animal and in vitro tissue models. Utilize in vitro/in vivo wound healing models (rodent) to screen pharmacological interventions for the effective treatment of cutaneous sulfur mustard injuries. Continue instrumentation assessment to evaluate depth of cutaneous vesicant injury. Begin toxicogenomic studies to characterize the phases of wound healing in the hybrid sulfur mustard-thermal burn model (weanling pigs). Consider novel technologies to replace the M291 skin decontamination kit (SDK), and products that decontaminate wounds, and eyes.
- 5207 Therapeutics, Medical Toxicology - Non Traditional Agents (NTA) and Other Agents - This area will investigate the potential for transient or sustained systemic toxicity resulting from exposure to NTAs and selected chemical warfare agents. Efforts will seek to identify mechanisms of toxicity and to establish a scientifically-defendable quantitative means of predicting consequent health effect in human operators. Emphasis will be on developing computational tools that extend the utility of laboratory data for improving operational risk assessment and countermeasure therapy design.

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)

DATE: **February 2006**

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**TC2**

FY 2007 Planned Program (Cont):

- 722 Therapeutics, Respiratory and Systemic - Refine planned animal models to interface with screening protocols. Identify relevant endpoints for in vivo models. Complete studies to identify lead compounds as a medical countermeasure(s) therapy(ies) against multiple agent exposures. Develop screening protocol to evaluate and down-select candidate compounds.
- 868 Animal Models - Continue advanced non-human primate testing for chemical warfare agent exposure. Evaluate alternate models to meet FDA rules in a cost-effective manner.

Total 20263

	FY 2005	FY 2006	FY 2007
SBIR/STTR	0	229	0

FY 2006 Planned Program:

- 229 SBIR

Total 229

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)

DATE: **February 2006**

BUDGET ACTIVITY: **RDT&E DEFENSE-WIDE/ BA2 - Applied Research**

PE NUMBER AND TITLE: **0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**

PROJECT: **TC2**

C. Other Program Funding Summary:

	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011	To Compl	Total Cost
TC3 MEDICAL CHEMICAL DEFENSE (ATD)	12125	23863	18893	31812	31656	32621	33785	Cont	Cont

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CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)

DATE: **February 2006**

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**TR2**

COST (In Thousands)		FY 2005 Actual	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	FY 2010 Estimate	FY 2011 Estimate	Cost to Complete	Total Cost
TR2	MEDICAL RADIOLOGICAL DEFENSE (APPLIED RESEARCH)	0	295	1575	2961	4550	4926	5388	Continuing	Continuing

A. Mission Description and Budget Item Justification:

Project TR2 MEDICAL RADIOLOGICAL DEFENSE (APPLIED RESEARCH): This project funds applied research on the development of pretreatments to provide an effective medical defense against validated radiological threats. Innovative technical approaches and advances will be incorporated to obtain medical systems designed to provide enhanced protection against exposure to radiological threats. Program objectives focus on mitigating the health consequences from exposures to ionizing radiation that represent a significant threat to US forces under 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 short- and long-term risks of adverse health consequences. Accurate models to predict casualties will promote effective command decisions and force structure planning to ensure mission success. This project addresses the Joint Requirements Office (JRO) critical capability gaps identified in the baseline capability assessment performed in FY03. The specific critical capability gap addressed is gap #16 (Medical Prophylaxes - FDA Approval for radiological prophylaxes).

B. Accomplishments/Planned Program

	FY 2005	FY 2006	FY 2007
Radioprotectants	0	293	1575

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)

DATE: **February 2006**

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA2 - Applied Research	**0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**	**TR2**

FY 2006 Planned Program:

- 293 Radioprotectants - Identify and test, from a prioritized list of approximately 20 agents, two candidates for efficacy in a rodent model; the degree of protection at a radiation dose that normally causes approximately 90% lethality within 30 days (Lethal Dose (LD) 90/30). Develop new pre- and post-exposure treatment products that will protect against and/or mitigate the effects of short- and long-term consequences of external radiation exposure and/or internal contamination with radionuclides. Demonstrate immunomodulators (e.g., cytokines, growth factors, and defensins) and hematopoietic cell transplantation approaches to stimulate innate and adaptive immunological responses and reconstruction approaches to mitigate primary and secondary infections from a weakened immune system.

Total 293

FY 2007 Planned Program:

- 1575 Radioprotectants - Evaluate three to four new compounds for efficacy at the LD 90/30. Assess the more promising candidates to determine the dose-reduction factor (DRF) for radioprotection and develop protocols for evaluation in a non-human primate model system. Demonstrate the efficacy of combined agents that confer protective or palliative effects against all types of radiation with minimal or few toxic side effects. Develop current Good Laboratory Practice (cGLP) capacity test capability and evaluate candidate products in appropriate animal models of radiation-induced syndromes.

Total 1575

	FY 2005	FY 2006	FY 2007
SBIR/STTR	0	2	0

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)

DATE: **February 2006**

BUDGET ACTIVITY: **RDT&E DEFENSE-WIDE/ BA2 - Applied Research**

PE NUMBER AND TITLE: **0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)**

PROJECT: **TR2**

FY 2006 Planned Program:

- 2 SBIR

Total 2

C. Other Program Funding Summary:

	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011	To Compl	Total Cost
TR3 MEDICAL RADIOLOGICAL DEFENSE (ATD)	0	0	2162	4441	4203	4523	6731	Cont	Cont