| Exhibit R-2, RDT&E Budget Item Justification: PB 2022 Chemical and Biological Defense Program | Date: May 2021 |
|---|---|
| **Appropriation/Budget Activity**<br>0400: *Research, Development, Test & Evaluation, Defense-Wide* / BA 2: *Applied Research* | **R-1 Program Element (Number/Name)**<br>PE 0602384BP / *CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)* |

| COST ($ in Millions) | Prior Years | FY 2020 | FY 2021 | FY 2022 Base | FY 2022 OCO | FY 2022 Total | FY 2023 | FY 2024 | FY 2025 | FY 2026 | Cost To Complete | Total Cost |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Total Program Element | - | 201.105 | 201.807 | 206.956 | - | 206.956 | - | - | - | - | - | - |
| CB2: *Chemical Biological Defense (Applied Research)* | - | 82.539 | 103.497 | 104.362 | - | 104.362 | - | - | - | - | - | - |
| NT2: *Non-Traditional Agents Defense (Applied Research)* | - | 49.222 | 0.000 | 0.000 | - | 0.000 | - | - | - | - | - | - |
| TM2: *Techbase Medical Defense (Applied Research)* | - | 69.344 | 98.310 | 102.594 | - | 102.594 | - | - | - | - | - | - |

**A. Mission Description and Budget Item Justification**

The projects in this program element (PE) support applied research in the areas of physical technologies, Non-Traditional Agent (NTA) medical and physical defense technologies, and medical technologies. Major efforts support development of vaccines, therapeutics, next generation diagnostics systems, next generation chemical detectors, nerve agent pretreatments, and individual protection advances.

Individual projects include:
- Chemical Biological Defense (CB2): continual improvements in CB physical sciences defense materiel, including contamination avoidance, decontamination, detection and protection technologies, as well as biological weapon/agent surveillance (e.g. CB protective materials, textiles, and filtration, sensors and sensing algorithms, effects modeling, chemical formulations, processes, and methods for hazard mitigation).

- NTA Defense (NT2): supports all NTA efforts (both medical and non-medical) including pretreatments, therapeutics, detection, threat agent science, modeling, protection and hazard mitigation and characterization of emerging threats. Starting in FY21, a portion of the NTA lines have been merged into RDT&E Projects CB3, Chemical Biological Defense, and TM3, Techbase Medical Defense. The administrative change is intended to improve S&T budget agility and transition efficiency.

- Techbase Medical Defense (TM2): development of antidotes, drug treatments, disease surveillance and point-of-need diagnostic devices, patient decontamination and medical technologies management (e.g. drug discovery and platform technology development, biomarkers and assay development useful in drug development and diagnostics, human mimicking devices and regulatory science).

CBDP S&T Applied Research Stakeholders: U.S. Army Combat Capabilities Development Command Chemical Biological Center (DEVCOM CBC), United States Army Medical Research Institute of Infectious Diseases (USAMRIID), United States Army Medical Research Institute of Chemical Defense (USAMRICD), United States Army Natick Soldier Systems Center, Naval Research Lab (NRL), Air Force Research Lab (AFRL), among others. The intent is to maintain strategic partnerships with the Department of Defense (DoD) Service communities for mission success across the enterprise through collaborative planning and programming maintaining budget assurance.

| Exhibit R-2, RDT&E Budget Item Justification: PB 2022 Chemical and Biological Defense Program | Date: May 2021 |
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| **Appropriation/Budget Activity**<br>0400: *Research, Development, Test & Evaluation, Defense-Wide* / BA 2: *Applied Research* | **R-1 Program Element (Number/Name)**<br>PE 0602384BP / *CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)* |

Efforts under this PE will transition to or will provide risk reduction for Advanced Technology Development (PE 0603384BP), Advanced Component Development and Prototypes (PE 0603884BP), and System Development and Demonstration (PE 0604384BP) activities.

| B. Program Change Summary ($ in Millions) | FY 2020 | FY 2021 | FY 2022 Base | FY 2022 OCO | FY 2022 Total |
|---|---|---|---|---|---|
| Previous President's Budget | 215.057 | 201.807 | 208.635 | - | 208.635 |
| Current President's Budget | 201.105 | 201.807 | 206.956 | - | 206.956 |
| Total Adjustments | -13.952 | 0.000 | -1.679 | - | -1.679 |
| • Congressional General Reductions | - | - | | | |
| • Congressional Directed Reductions | - | - | | | |
| • Congressional Rescissions | - | - | | | |
| • Congressional Adds | 0.000 | - | | | |
| • Congressional Directed Transfers | 0.000 | - | | | |
| • Reprogrammings | -8.499 | - | | | |
| • SBIR/STTR Transfer | -5.453 | - | | | |
| • Other Adjustments | 0.000 | - | -1.679 | - | -1.679 |

**Change Summary Explanation**

Funding: FY20 (-$8.501 Million): Internal Reprogramming (FY20-31 IR) for the Coronavirus Aid, Relief, and Economic Security (CARES) Act to conduct rapid assessments and characterizations of emerging pathogens (+$1.500 Million); below threshold reprogramming to Advanced Technology Development for COVID-19 SARS-CoV-2 vaccine development project (-$5.404 Million) and medical defense pretreatments efforts (-$3.909 Million); below threshold reprogramming to RDT&E Management Support for support to laboratory infrastructure for laboratory operations, facilities sustainment, and regulatory compliance for critical chemical biological defense activities at USAMRIID and USAMRICD (-$0.688 Million).

FY20 (-$5.453 Million): Transfer of funding to support Small Business Innovative Research/Small Business Technology Transfer efforts.

FY22: (-$1.679 Million): Program adjustments for Emerging Threat Rapid Response Capabilities (+$2.300 Million); Departmental reduction to account for the availability of prior year execution balances (-$1.931 Million); and Departmental inflation/travel adjustments (-$2.048 Million).

Schedule: N/A

Technical: N/A

| Exhibit R-2A, RDT&E Project Justification: PB 2022 Chemical and Biological Defense Program | | | Date: May 2021 |
|---|---|---|---|
| Appropriation/Budget Activity<br>0400 / 2 | R-1 Program Element (Number/Name)<br>PE 0602384BP / *CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)* | Project (Number/Name)<br>CB2 / *Chemical Biological Defense (Applied Research)* | |

| COST ($ in Millions) | Prior Years | FY 2020 | FY 2021 | FY 2022 Base | FY 2022 OCO | FY 2022 Total | FY 2023 | FY 2024 | FY 2025 | FY 2026 | Cost To Complete | Total Cost |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| CB2: *Chemical Biological Defense (Applied Research)* | - | 82.539 | 103.497 | 104.362 | - | 104.362 | - | - | - | - | - | - |

**A. Mission Description and Budget Item Justification**

Project CB2 provides physical science applied research to develop future, multi-disciplinary, and multi-functional capabilities in life sciences, physical sciences, environmental sciences, mathematics, cognitive sciences, and engineering. Efforts in this project support the seamless integration of state-of-the-art-technologies into a collection of systems across the spectrum of capabilities required to support chemical and biological defense missions.

Individual efforts in this project include:
- Protection and hazard mitigation focuses on providing technologies that protect from and reduce the impact of chemical/biological threat or hazard to the Warfighter, weapons platforms, and structures.
- Detection focuses on developing technologies for remote and point detection and identification of chemical and biological agents.
- Decision analysis and management focuses on advanced hazard prediction, medical and epidemiological modeling of biological agents, operational effects and risk assessment, and systems performance modeling.
- Warning and reporting focuses on methods of alerting to chemical or biological threat agent releases and exposures.
- Threat agent science is devoted to characterizing threat agents and the hazards they present in terms of agent fate in the environment, toxicology, and pathogenicity, and focuses on the horizontal integration of CB defensive technologies in support of the Joint Services.
- Non-Traditional Agent (NTA) Defense including pretreatments, therapeutics, detection, threat agent science, modeling, protection and hazard mitigation and characterization of emerging threats.

Project NT2, Techbase Non-Traditional Agents Defense, will merge into this Project starting in FY21.

FY21-22 reorganizes, renames legacy Bullet titles and introduces new Bullets (Thrust Areas). These new "Thrust" titles are in line with the CBDP Core Capability Areas and intended to provide more detail and traceability from the S&T program to advanced development.

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2020 | FY 2021 | FY 2022 |
|---|---|---|---|
| ***Title:*** 1) CARES Act: - ProBE: Proteomic/Multi-omic Biothreat Evaluation<br>***Description:*** Provides the ability to conduct comprehensive assessments and characterizations of emerging pathogens using interdisciplinary approaches. | 1.000 | - | - |
| ***Title:*** 2) CARES Act: Reusable N95 Masks to DEVCOM CBC | 0.500 | - | - |

| Exhibit R-2A, RDT&E Project Justification: PB 2022 Chemical and Biological Defense Program | | Date: May 2021 |
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| **Appropriation/Budget Activity**<br>0400 / 2 | **R-1 Program Element (Number/Name)**<br>PE 0602384BP / *CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)* | **Project (Number/Name)**<br>CB2 / *Chemical Biological Defense (Applied Research)* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2020 | FY 2021 | FY 2022 |
|---|---|---|---|
| ***Description:*** Provides reusable N95 Masks to the Combat Capabilities Development Command (DEVCOM) Chemical Biological Center (CBC). | | | |
| ***Title:*** 3) Internal COVID: Virus decon to DEVCOM CBC<br>***Description:*** Virus decontamination to DEVCOM CBC. | 0.054 | - | - |
| ***Title:*** 4) Internal COVID: Portable bio containment module testing at DEVCOM SC.<br>***Description:*** Portable bio containment module testing at DEVCOM SC. | 0.034 | - | - |
| ***Title:*** 5) Detection Sensor Technologies<br>***Description:*** Focus of this effort is to develop capabilities to detect and identify chemical and biological threats. This activity includes development of point, remote, or standoff sensors as appropriate, to address both conventional and non-traditional chemical and biological threats. These efforts are being developed to further the detection capability for early warning of contamination exposure to the warfighter. This effort is being separated into five thrust areas starting in FY21: Distributed CB Reconnaissance, Enhanced/Emerging Biothreat Sensing, Expeditionary Analytical Toolkit (ExAnT), Unattended Perimeter Monitoring, and Unconventional Detection Modality. | 22.541 | - | - |
| ***Title:*** 6) Distributed CB Reconnaissance<br>***Description:*** Develop distributed chemical and biological reconnaissance tools to enhance early warning and situation awareness of chemical and biological threats to include low cost point sensor and sensing/collection systems for manned and unmanned platforms.<br>***FY 2021 Plans:***<br>- Identify strategic points of placement for sensor integration by conducting modeling research on agent dispersal patterns; demonstrate in-flight collection and detection for sensors integrated onto unmanned aerial platforms.<br>- Evaluate enhanced technologies on manned and unmanned platforms for early warning and integrated threat awareness.<br>***FY 2022 Plans:***<br>- Evaluate low size, weight, power, and cost technologies for near-real time detection capabilities for deployable or distributed biological and chemical sensing for hazard awareness and assessment of operational environments.<br>- Identify innovative solutions to increase situational awareness using manned and unmanned platforms and provide operational advantages to the Warfighter.<br>***FY 2021 to FY 2022 Increase/Decrease Statement:*** | - | 4.031 | 3.328 |

| Exhibit R-2A, RDT&E Project Justification: PB 2022 Chemical and Biological Defense Program | | Date: May 2021 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 2 | **R-1 Program Element (Number/Name)**<br>PE 0602384BP / *CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)* | **Project (Number/Name)**<br>CB2 / *Chemical Biological Defense (Applied Research)* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2020 | FY 2021 | FY 2022 |
|---|---|---|---|
| Decrease due to change in program/project schedule. | | | |
| ***Title:*** 7) Enhanced/Emerging Biothreat Sensing<br><br>***Description:*** Establish capability to rapidly develop sensors to detect enhanced or emerging biological threats via quickly adaptable or analyte-agnostic laboratory and field-forward detection capabilities. This will provide improved detection capabilities for unknown or novel threats across the spectrum of detection and validation assets. This thrust area leverages multi-omics data science to inform rational and rapid development of synthetic biological sensing platforms as well as improved laboratory methods.<br><br>***FY 2021 Plans:***<br>- Continue development of algorithms and laboratory workflows to identify threats in unknown samples.<br>- Continue development of far-forward pathogen agnostic sensing toolkit.<br>- Continue development of ruggedized, scalable sensor with adaptable design.<br>- Continue development of sample stabilization methods.<br>- Begin automated in-silico design to expedite assay development.<br>- Examine potential solutions for augmenting or replacing current lateral flow assays.<br><br>***FY 2022 Plans:***<br>- Continue development of algorithms and laboratory workflows to identify threats in unknown samples.<br>- Continue development of far-forward pathogen agnostic sensing toolkit.<br>- Continue automated in-silico design to expedite assay development.<br>- Accelerate transitions of multi-omic data tools from interagency partners, leveraging increasing understanding of the fundamental biology of emerging and engineered threats to inform development of agile sensors with optimized detection targets and capabilities.<br><br>***FY 2021 to FY 2022 Increase/Decrease Statement:***<br>Increase due to accelerated development effort. | - | 7.055 | 9.825 |
| ***Title:*** 8) Expeditionary Analytical Toolkit (ExAnT)<br><br>***Description:*** Keeping the warfighter ahead of traditional and emerging chemical threats in complex environments by developing a suite of expeditionary chemical sensors with modernized detection technologies for traditional threats while enhancing detection capabilities for non-traditional, emerging, and mixed chemical hazards.<br><br>***FY 2021 Plans:***<br>- Continue development of detection technologies to provide unattended monitoring for early indication of airborne chemical threats. | - | 2.861 | 3.333 |

| Exhibit R-2A, RDT&E Project Justification: PB 2022 Chemical and Biological Defense Program | | Date: May 2021 |
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| **Appropriation/Budget Activity**<br>0400 / 2 | **R-1 Program Element (Number/Name)**<br>PE 0602384BP / *CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)* | **Project (Number/Name)**<br>CB2 / *Chemical Biological Defense (Applied Research)* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2020 | FY 2021 | FY 2022 |
|---|---|---|---|
| - Provide a comprehensive characterization of common pre-cursor chemicals, intermediates, and yielded synthetic opioids to support optical detection enhancement.<br>- Develop low SWaP proximate sensors to detect deposited chemical hazards to support tactical and dismounted site assessment missions.<br>- Provide advanced sensing capability for low volatility chemicals and emerging threats to protect the Warfighter.<br>***FY 2022 Plans:***<br>- Support expeditionary forces in leveraging reach-back capabilities for identification purposes.<br>- Continue to develop advance detection capabilities to detect chemical warfare agents in complex and obscurant-heavy environments.<br>- Evaluate detectors ability to measure hazards in complex environments and samples.<br>- Advance detection capabilities by developing sensor platforms for integration into a portable device.<br>- Anticipate future detection capability needs to support the warfighter in CB-contested operational environments.<br>- Evaluate and transition compact vapor detectors for the Warfighter.<br>- Continue to develop novel data processing and data analysis algorithms based on machine learning techniques.<br>***FY 2021 to FY 2022 Increase/Decrease Statement:***<br>Minor change due to routine program adjustments. | | | |
| ***Title:*** 9) Unattended Perimeter Monitoring<br>***Description:*** Develop automated technologies to improve detection of aerosolized hazards while minimizing or removing user intervention to enable a reliable detect-to-warn capability, providing a capability for unattended monitoring of perimeters for temporary defense positioning, including base camps, to enable early indication of threats. This thrust area will evaluate current and novel technologies to provide improved chemical threat detection and automated biological detection capabilities.<br>***FY 2021 Plans:***<br>- Modernize unattended perimeter monitoring technologies to reduce false alarms and increase confidence in reporting.<br>- Refine trigger, collector, and detector/identifier technologies.<br>***FY 2022 Plans:***<br>- Evaluate the use of machine learning into detector/identifier technologies to further reduce false reporting due to environmental factors.<br>- Continue development of fully-automated biosurveillance system capable of air sample collection, sample preparation, and analysis.<br>***FY 2021 to FY 2022 Increase/Decrease Statement:*** | - | 2.436 | 4.114 |

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| B. Accomplishments/Planned Programs ($ in Millions) | FY 2020 | FY 2021 | FY 2022 |
|---|---|---|---|
| Increase due to change in program/project technical parameters. | | | |
| ***Title:*** 10) Unconventional Detection Modalities<br><br>***Description:*** Targeted set of programs pushing the boundaries of sensor development by pulling technologies developed from academia and basic research to be integrated into early detection prototypes. These technologies focus on keeping the warfighter ahead of the chemical and biological threats with portable, low SWaP detectors that will protect the general forces and enhance operations on the battlefield by providing warning and field analytics.<br><br>***FY 2021 Plans:***<br>- Continue design and integration of monolithic interferometer.<br>- Continue to synthesize and further assess SIC materials by coating various surface coupons.<br>- Continue and validate chemical detection modalities utilizing Waveguide Enhanced Raman Spectroscopy (WERS) and Refractive Index sensing.<br>- Conduct field testing of detection prototypes using nanoparticles and voltammetry electrochemistry.<br>- Continue model development for machine learning algorithms.<br>- Continue development of detection of BWA using cell-free platforms onto an integrated prototype.<br>- Conduct a low SWAP-C demonstration using cell-based platforms<br>- Develop prototype using optical light scattering for biological detection.<br>- Validate gene deletion in bacterial pathogens.<br><br>***FY 2022 Plans:***<br>- Conduct detection sensing validation for detection by utilizing nanoparticles and voltammetry electrochemistry.<br>- Conduct model testing and validation of machine learning algorithms for chemical detection sensors.<br>- Miniaturize and refine optical light scattering prototype.<br>- Conduct live-agent testing using cell-free platforms.<br><br>***FY 2021 to FY 2022 Increase/Decrease Statement:***<br>Decrease due to change in program/project technical parameters. | - | 7.183 | 4.997 |
| ***Title:*** 11) Material Contamination Mitigation<br><br>***Description:*** Develop highly effective non-traditional or novel decontamination technologies that integrate with current procedures and support non-material improvements of the overall decontamination effort. This effort is being separated into three thrust areas starting in FY21: Enhanced Survivability Coatings, Equipment Decontamination, and Wide Area Decontamination. | 9.738 | - | - |
| ***Title:*** 12) Enhanced Survivability Coatings | - | 3.202 | 2.436 |

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| B. Accomplishments/Planned Programs ($ in Millions) | FY 2020 | FY 2021 | FY 2022 |
|---|---|---|---|
| ***Description:*** This effort supports the Materiel Contamination Mitigation Core Capability Area. Military equipment coatings are challenging and logistically intensive to decontaminate. Efforts within this thrust seek to produce enhanced coatings that increase chemical warfare agent survivability and decontaminability of military equipment to levels comparable to that of stainless steel. Improved coatings will resist chemical agent absorption and be quickly decontaminated in field, to rapidly return equipment to mission operations level.<br><br>***FY 2021 Plans:***<br>- Continue evaluating polymer coatings as potential temporary or permanent military equipment coatings to decrease logistical burden of decontamination in support of CBRN Coatings, Coverings, and Protective Overlays Program of Record.<br>- Increase chemical agent resistance of current military coatings through development and testing of novel temporary coatings to reduce the spread of contamination and enable more facile decontamination of military assets.<br>- Continue to improve equipment coatings through bio-inspired surface treatments to repel agents of interest from current military equipment coatings.<br><br>***FY 2022 Plans:***<br>- Improve success of decontamination through the evaluation and incorporation of appliques (to include chemical transport studies in current military coatings, novel coatings characterization, thin film overcoats, strippable coat, reactive coat, and lock-down coats) in support of CBRN Coatings, Coverings, and Protective Overlays Program of Record.<br>- Incorporate bio-inspired surface treatments for equipment coatings to repel agents of interest from current military equipment coatings.<br><br>***FY 2021 to FY 2022 Increase/Decrease Statement:***<br>Decrease due to change in program/project technical parameters. | | | |
| ***Title:*** 13) Equipment Decontamination<br><br>***Description:*** This effort supports the Materiel Contamination Mitigation Core Capability Area. The Warfighter has a limited capability to decontaminate personal equipment, weapons, vehicles, ships, and facilities; Sensitive equipment (weapon system optics, electronic equipment, interior spaces, and aircraft); and hazardous waste. Efforts within this thrust seek to develop decontaminant formulations and procedures that reduce or eliminate residual contamination hazards; enable unit-level decontamination with rapid unmasking; reduce logistic needs (need for water); enable rapid sorting of clean from dirty to rapidly return high-value equipment to normal use; and develop improved realistic test methods.<br><br>***FY 2021 Plans:***<br>- Transition disclosure/decontamination assurance technologies low light formulation to enhance agent disclosure/ decontamination assurance technologies to the Contamination Indicator Decontamination Assurance System program. | - | 2.079 | 3.150 |

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| B. Accomplishments/Planned Programs ($ in Millions) | FY 2020 | FY 2021 | FY 2022 |
|---|---|---|---|
| - Complete and transition biological hot air decontamination technology for aircraft and sensitive equipment to the Joint Biological Agent Decontamination System (JBADS) Program of Record.<br>- Complete operational user assessment for Sprayable Decontaminant Slurry technology for tactical level equipment decontamination.<br>- Complete optimization of chemical hot air decontamination process and transition to the Service Equipment Decontamination System (SEDS) Program of Record.<br>***FY 2022 Plans:***<br>- Begin integrating contamination mitigation technologies by advancing the proof of concept for hot-air CWA decontamination by validating the operational performance envelope. Successful efforts will result in improved efficacy, materials compatibility, flexibility, and reduced logistical burden compared to existing and emerging decontamination program requirements.<br>- Transition Sprayable Decontaminant Slurry technology for immediate chemical warfare agent decontamination of equipment to the Service Equipment Decontamination System (SEDS).<br>***FY 2021 to FY 2022 Increase/Decrease Statement:***<br>Increase due to change in program/project technical parameters. | | | |
| ***Title:*** 14) Wide Area Decontamination | - | 0.867 | - |
| ***Description:*** This effort supports the Materiel Contamination Mitigation Core Capability Area. Warfighters lack capability to rapidly restore critical DoD infrastructure (e.g., sea port or air base) that will mitigate contamination spread and enable normal, unprotected operations. Efforts within this thrust seek to improve contamination mitigation logistics/cost reduction, effectiveness, compatibility/safety, and environmental compatibility.<br>Wide Area Decontamination efforts will not be conducted during FY22-FY25 due to funding reductions. Efforts are scheduled to resume in FY26.<br>***FY 2021 Plans:***<br>- Continue Wide Area Decontamination efforts (funded as BA3 in FY 2020) to examine analytical methods, test procedures, and candidate packaged commercial chemicals as decontaminants for decontamination of chemical agents on concrete, asphalt and soil.<br>- Assess packaged commercial chemicals as decontaminants and barrier polymers on concrete, asphalt, and soil substrates for effectiveness, availability, and sprayability/scalability.<br>- Complete and publish Wide Area Decontamination decontaminant assessment report for chemical agents.<br>***FY 2021 to FY 2022 Increase/Decrease Statement:*** | | | |

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| B. Accomplishments/Planned Programs ($ in Millions) | FY 2020 | FY 2021 | FY 2022 |
|---|---|---|---|
| Minor change due to routine program adjustments. | | | |
| ***Title:*** 15) Warning and Reporting<br>***Description:*** Integrate and fuse disparate sensor data, leverage non-invasive physiological data for detection of threat exposure prior to symptom onset, and provide timely data-driven predictions and warnings. This effort is transitioning to the CBRN Battlespace Surveillance, Alerting & Response thrust area starting in FY21. | 11.159 | - | - |
| ***Title:*** 16) CBRN Battlespace Surveillance, Alerting & Response<br>***Description:*** To improve upon the Department of Defense's capability to detect, identify, alert, and responds to deliberate releases and naturally occurring outbreaks of chemical and biological threat agents. Current predictive algorithms in development by JSTO are based on large in-hospital datasets from patients with comorbidities. Improving on the applicability and efficacy of these algorithms will focus on large, real-time human data collects of chemical and biological agent / agent proxy exposures. Additionally, studies will focus on examining the feasibility of specifically isolating indicators of respiratory infection, determining severity of infection, and predicting return to mission readiness after exposure. This capability will enable early implementation of countermeasures such as isolation, quarantine, and removal from an area, thus potentially reducing transmission, morbidity, and mortality rates. The maturation of algorithms will incorporate Machine Learning (ML) approaches for refining sensitivity and specificity.<br><br>***FY 2021 Plans:***<br>- Continue to expand on wearable device-based non-invasive biomarker analysis for pre-symptomatic indication of chemical or biological exposure.<br>- Enhance early warning algorithm development for predicting altered health severity and duration to inform on warfighter time-to mission-readiness.<br>- Continue to develop ML algorithms to detect signatures of genetically engineered pathogens.<br>***FY 2022 Plans:***<br>- Continue to expand wearable device-based non-invasive biomarker analysis for pre-symptomatic indication of chemical or biological exposure.<br>- Complete early warning algorithm development for predicting altered health severity and duration to inform warfighter time-to mission-readiness.<br>- Continue to develop ML algorithms to detect signatures of genetically engineered pathogens<br>- Continue to develop predictive algorithms and analytic tools utilizing Artificial Intelligence (AI) and ML techniques to allow for rapid response to Emerging Threats. | - | 8.625 | 9.459 |

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| B. Accomplishments/Planned Programs ($ in Millions) | FY 2020 | FY 2021 | FY 2022 |
|---|---|---|---|
| - Initiate the development of AI based drug discovery algorithms for Emerging Threats.<br><br>***FY 2021 to FY 2022 Increase/Decrease Statement:***<br>Increase due to change in program/project technical parameters. | | | |
| ***Title:*** 17) Decision Analysis and Management<br><br>***Description:*** Improve battlespace awareness and support decision-making by predicting hazardous material releases and resulting human effects. Provide tools to enable the assessment and mitigation of impacts at personnel, system, tactical, operational, and strategic levels. Develop CBRN data sharing capabilities and information resources. This effort is being separated into two thrust areas starting in FY21: CBRN Decision Aids and CBRN Situational Awareness. | 19.181 | - | - |
| ***Title:*** 18) CBRN Decision Aids<br><br>***Description:*** In order to unencumber the warfighter at the tactical edge, JSTO will continue to develop and field CBRN Decision Aids on End User Devices (EUDs) in both connected and disconnected operations. Capabilities will focus on utilizing automation, reducing the burden experienced by the warfighter, while providing accurate, actionable information. During this time period, a focus will be put on developing a Contamination Avoidance Decision Aid to inform the warfighter on how to avoid, respond to and plan routes around CB hazards.<br><br>Another area of focus will be the development of Autonomous Asset Guidance. This capability will be used in conjunction with other capabilities developed under the CBRN Decision Aids portfolio to optimize the use of Autonomous Assets and reduce the burden incurred by the warfighter in order to operate them. This capability will also aim to incorporate, fuse and utilize data from Autonomous Assets to improve and refine other CBRN Decision Aids.<br><br>***FY 2021 Plans:***<br>- Develop a sensor model toolbox application for rapid development of new sensor models<br>- Continue development of algorithms to optimize the path of moving sensors for detection and source term estimation and develop the capability to react to events.<br>- Continue development of warning and decision aids for tactical users leveraging the compute resources resident on EUDs. Explore the use of augmented reality to provide chemical and biological threat situational awareness in head-mounted visual displays.<br><br>***FY 2022 Plans:***<br>FY22:<br>- Continue development of warning and decision aids for tactical users leveraging the compute resources resident on EUDs. | - | 4.903 | 3.100 |

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| B. Accomplishments/Planned Programs ($ in Millions) | FY 2020 | FY 2021 | FY 2022 |
|---|---|---|---|
| - Initiate the use of augmented reality to provide chemical and biological threat situational awareness in head-mounted visual displays.<br><br>***FY 2021 to FY 2022 Increase/Decrease Statement:***<br>Decrease due to change in program/project technical parameters. | | | |
| ***Title:*** 19) CBRN Situational Awareness<br><br>***Description:*** To enhance CB Situational Awareness, JSTO will expand the types of threats that can be modeled with hazard assessment capabilities to include fixed-wing and rotary-wing drones of interests. These capabilities will allow for single drones and swarms to be modeled.<br><br>Virtual Reality (VR) and Augmented Reality (AR) technologies will be leveraged to develop CB focused training and mission rehearsal capabilities that will be integrated into systems widely used by the Joint Force. Virtual training environments will be developed to implement, visualize and account for hazard source terms and plumes generated by transport and dispersion (T&D) models Augmented Reality applications will also be explored for tactical use to maximize warfighter CB situational awareness on the battlefield.<br><br>JSTO will modernize hazard modeling capabilities by adopting a modular framework and integrating across Service command and control systems to operationalize Reachback support. JSTO will further enhance hazard modeling by creating a seamless indoor-to-outdoor T&D modeling capability and improve urban T&D modeling to support operations in urban and mixed environments. New state-of-the-art computational fluid dynamics modeling techniques and their exploitation of the latest computing resources will be leveraged to increase both speed and accuracy.<br><br>JSTO will develop CB health effect modeling software and analytic tools to support force readiness and facilitate medical planning against chemical and biological agents. Epidemiological models will be developed that quantify and visualize mission operational impacts from exposure to, and spread of, infectious biological threat agents to DoD relevant populations. Additionally, JSTO will leverage Threat Agent Science (TAS) data to enhance capabilities for modeling health effects and host pathogen interactions from exposures to traditional and non-traditional CB agents. This will provide the warfighter with more accurate casualty estimates accounting for human health effects.<br><br>***FY 2021 Plans:***<br>- Continue development of coupled indoor and outdoor dispersion models for enhanced hazard prediction in urban environments.<br>- Conduct field trial to collect validation data for coupled indoor and outdoor dispersion models.<br>- Complete development of microscale transport and dispersion software for improved hazard prediction in urban environments.<br>- Continue development of next generation littoral and liminal waterborne modeling system. | - | 12.891 | 10.894 |

| Exhibit R-2A, RDT&E Project Justification: PB 2022 Chemical and Biological Defense Program | | Date: May 2021 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 2 | **R-1 Program Element (Number/Name)**<br>PE 0602384BP / *CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)* | **Project (Number/Name)**<br>CB2 / *Chemical Biological Defense (Applied Research)* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2020 | FY 2021 | FY 2022 |
|---|---|---|---|
| - Continue to develop models to provide operationally relevant outputs to support medical decision making. Integrate outputs into existing comprehensive epidemiological modeling tool.<br>- Continue to develop ML algorithms for disease prediction and forecasting for mobile platforms.<br>- Initiate efforts to develop VR/AR synthetic training environment.<br>- Initiate biological agent modeling into the NHRC's JMPT.<br>***FY 2022 Plans:***<br>- Complete development of coupled indoor and outdoor dispersion models for enhanced hazard prediction in urban environments.<br>- Complete field trial to collect validation data for coupled indoor and outdoor dispersion models.<br>- Complete development of next generation littoral and liminal waterborne modeling system.<br>- Continue to enhance CB situational awareness capabilities for integration into Heads up Display (HUD) technologies.<br>***FY 2021 to FY 2022 Increase/Decrease Statement:***<br>Decrease due to change in program/project technical parameters. | | | |
| ***Title:*** 20) Threat Agent Sciences<br>***Description:*** Supports defensive countermeasure development against CB threats by delivering the scientific data, understanding, and relevant human estimates of the hazards posed to humans by exposure to CB agents. Toxicological and/or infectious-dose information and environmental response supports development and/or enhancement of both operational risk and exposure guidelines; identifies gaps in detection and protection; informs decontamination procedures; and supports the development of medical countermeasures. Knowledge generated from this program is used to inform understanding of hazards, hazard prediction models, and materiel and countermeasure development. This effort is being separated into five thrust areas starting in FY21: Employment Characterization, Environmental Response, First Look (Chemical and Biological), Host Response, and Technical Surprise. | 11.711 | - | - |
| ***Title:*** 21) Employment Characterization<br>***Description:*** Employment Characterization studies help refine threat assessments and potential impacts of indoor and/or outdoor releases of threat agents on CBDP operations, strategy, and capabilities.<br>***FY 2021 Plans:***<br>- Review state of knowledge on agent employment (laboratory and outdoors) to identify gaps and threat agent science assessment opportunities.<br>- Continue with evaluation of potential munitions for applicability to future threat based on performance characteristics.<br>- Continue studying scale employment methods and feasibility for emerging threat agents.<br>***FY 2022 Plans:*** | - | 4.943 | 4.159 |

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| B. Accomplishments/Planned Programs ($ in Millions) | FY 2020 | FY 2021 | FY 2022 |
|---|---|---|---|
| - Continue to review state of knowledge on agent employment (laboratory and outdoors) to identify gaps and threat agent science assessment opportunities.<br>- Provide munitions evaluation to modelers and stakeholders, and follow with a gap analysis to determine knowledge gaps for future analysis.<br>- Continue studying scale employment methods and feasibility for emerging threat agents.<br>***FY 2021 to FY 2022 Increase/Decrease Statement:***<br>Decrease due to change in program/project technical parameters. | | | |
| ***Title:*** 22) Environmental Response<br>***Description:*** Environmental Response evaluates behavior of chemical and biological threat agents in the environment (including soil, water, and plants), on clothing, on and in structures, and on equipment supports model development and decision-making tools.<br>***FY 2021 Plans:***<br>- Continue delivering data on fate, persistence, viability and response of priority agents in various environments to inform hazard assessment.<br>- Continue assessing the impact of environmental factors on threat agent activity (persistence, viability, transport, degradation, resuspension, and decontamination) for both chemical and biological threats.<br>- Continue exploratory studies that analyze the state of the art for encapsulation technologies and methodologies.<br>- Assess the properties of anti-materiel agents and evaluate the efficacy of these agents including environmental stability and factors associated with performance against materials of interest.<br>- Identify and close knowledge gaps associated with the aerosol biology and its implications with the outdoor release of biological threats.<br>***FY 2022 Plans:***<br>- Continue delivering data on fate, persistence, viability and response of priority agents in various environments to inform hazard assessment (for chemical and biological threats).<br>- Continue assessing the impact of environmental factors on threat agent activity (persistence, transport, degradation, resuspension, and decontamination).<br>- Continue to identify and close knowledge gaps associated with the aerosol biology and its implications with the outdoor release of biological threats.<br>- Continue assessing anti-material agents, evaluate the efficacy of these agents, and measure their environmental stability and performance against materials of interest. | - | 5.491 | 5.548 |

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| B. Accomplishments/Planned Programs ($ in Millions) | FY 2020 | FY 2021 | FY 2022 |
|---|---|---|---|
| - Continue environmental stability efforts for toxin and viral threats, including the fundamental characteristics that influence viral stability.<br><br>***FY 2021 to FY 2022 Increase/Decrease Statement:***<br>Minor change due to routine program adjustments. | | | |
| ***Title:*** 23) First Look (Chemical and Biological)<br><br>***Description:*** First Look provides the initial characterization of potential CB threats, and provides a fundamental assessment of the potential risks they pose (including synthesis, growth, production, virulence, feasibility for weaponization and initial toxicology screening).<br><br>***FY 2021 Plans:***<br>- Finish priority Pharmaceutical based agent (PBA) assessments.<br>- Continue NTA evaluations<br>- Expand Biological First Look to assess additional emerging pathogens and novel toxins.<br>- Continue developing innovative laboratory tools and approaches to enable expedient characterization of emerging, or novel biological threats, including the understanding enabling technologies impact to gene modification/expression to assess toxin activity.<br>- Continue examining and developing advanced methods for threat agent characterization, including more complex agent mixtures or combinations.<br><br>***FY 2022 Plans:***<br>- Continue developing innovative laboratory tools and approaches to enable expedient characterization of emerging or novel biological threats (to include highly infectious and novel organisms), including understanding enabling technologies' impact to gene modification/expression and the ability to assess toxin activity.<br>- Continue developing advanced methods for threat agent characterization, including more complex agent mixtures or combinations.<br>- Begin evaluating findings of technological advancement implications to discounted threats study.<br><br>***FY 2021 to FY 2022 Increase/Decrease Statement:***<br>Minor change due to routine program adjustments. | - | 9.300 | 9.850 |
| ***Title:*** 24) Host Response<br><br>***Description:*** Host Response characterizes adverse effects (acute vs. chronic) from exposure to toxic chemical and/or infectious biological threat agents using operationally relevant exposure scenarios and exposure routes (e.g., .inhalation, dermal, ingestion, etc.) and appropriate assessment methods and models. | - | 11.800 | 15.200 |

| Exhibit R-2A, RDT&E Project Justification: PB 2022 Chemical and Biological Defense Program | | Date: May 2021 |
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| B. Accomplishments/Planned Programs ($ in Millions) | FY 2020 | FY 2021 | FY 2022 |
|---|---|---|---|
| ***FY 2021 Plans:***<br>- Execute a knowledge gap study focused on traditional biological agents to inform future threat agent science investments.<br>- Continue developing in silico predictive capabilities and models, linking the different properties to provide initial toxicological hazard assessment information on emerging threat compounds.<br>- Finalize validation of rapid threat assessment and microphysiological systems methods.<br>- Continue development of in vitro tools to provide acute toxicity and mechanisms of emerging threat agents using developed analytical processes rapid threat assessment and microphysiological systems methods.<br>***FY 2022 Plans:***<br>- Build on predictive methods and technologies for both chemical and biological agent characterizations.<br>- Deliver initial operational capacity for predictive toxicological analytical tools linking in silico analysis, in vitro assessments (activity, metabolism, etc), and refining quick turn estimates for emerging chemical threats, and informing follow on toxicological evaluations.<br>- Initiate studies to address host response areas identified by the FY21 gap analysis study for traditional biological agents.<br>***FY 2021 to FY 2022 Increase/Decrease Statement:***<br>Increase due to change in program/project technical parameters. | | | |
| ***Title:*** 25) Technical Surprise | - | 4.000 | 4.500 |
| ***Description:*** Technical Surprise assesses technological advancements for potential implications to the threat space. Technical Surprise will include horizon scanning to identify potential areas of concern as well as conduct technical assessments of emerging technological advancements (e.g. artificial intelligence, machine learning, quantum computing) of concern enabled by scientific advances which can be used for nefarious purposes.<br>***FY 2021 Plans:***<br>- Evaluate technologies that make threats more likely to survive employment/use.<br>- Complete retrosynthetic chemical analyses, and refer results to First look for further evaluation.<br>- Continue to maintain a watch on technology advancements and potential impacts to threat space or warfighter. Identify and assess the implications of progress and acceleration to-date for former technical hurdles being lowered or overcome<br>- Evaluate enabling areas of technological convergence that can potentially impact the ease and ability for nefarious actor use.<br>- Identify and assess the implications of the limitations and barriers associated with synthetic biology.<br>***FY 2022 Plans:*** | | | |

| Exhibit R-2A, RDT&E Project Justification: PB 2022 Chemical and Biological Defense Program | | Date: May 2021 |
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| **Appropriation/Budget Activity**<br>0400 / 2 | **R-1 Program Element (Number/Name)**<br>PE 0602384BP / *CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)* | **Project (Number/Name)**<br>CB2 / *Chemical Biological Defense (Applied Research)* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2020 | FY 2021 | FY 2022 |
|---|---|---|---|
| - Continue identifying and assessing technological advancements that will impact the chemical and biological threat space, including potential threats that are not specifically chemical or biological in nature, but have implications to chemical and biological defense capabilities.<br>- Continue a horizon scanning capability to provide situational awareness in assessing technological growth and convergence that can affect the chemical and biological threat space, while keeping abreast to changes in the nature of future threats.<br>- Continue the assessment of synthetic biological tools and other biotechnology developments that can enhance or alter the threat space.<br>***FY 2021 to FY 2022 Increase/Decrease Statement:***<br>Minor change due to routine program adjustments. | | | |
| ***Title:*** 26) Percutaneous Protection<br>***Description:*** Develop advanced ensemble prototypes with state-of-the art materials that address the full spectrum of threats and provide a range of solutions optimized for protection, thermal comfort, and mission performance. This effort is transitioning to the Dynamic Multifunction Materials for Second Skin thrust area starting in FY21. | 2.851 | - | - |
| ***Title:*** 27) Dynamic Multifunction Materials for Second Skin<br>***Description:*** This effort supports the Percutaneous Protection Core Capability Area. Efforts will utilize responsive technologies to provide chemical biological protective suits that adapt to the environment by synthesizing scaled samples via roll-to-roll manufacture which exhibit materials properties that reduce thermal burden and integrate with current combat garments. These technologies include interpenetrating polymer networks that will change moisture permeability and molecular selectivity on demand, and membranes with higher moisture vapor transfer rates than existing fabrics.<br>***FY 2021 Plans:***<br>- Continue to down-selecting processes for mounting responsive interpenetrating polymer network onto fabrics and begin agent testing.<br>- Continued efforts to scale and evaluate carbon nanotube membrane with for response to chemical and biological agents and begin agent testing.<br>***FY 2022 Plans:***<br>- Increase molecular selectivity of responsive interpenetrating polymers towards nerve and blister agents.<br>- Demonstrate and scale carbon nanotube membrane responsive textiles into garments that increase protection levels in response to chemical weapons agents while preserving moisture vapor transport rate; advance to BA3.<br>***FY 2021 to FY 2022 Increase/Decrease Statement:*** | - | 2.197 | 1.839 |

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|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 2 | **R-1 Program Element (Number/Name)**<br>PE 0602384BP / *CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)* | **Project (Number/Name)**<br>CB2 / *Chemical Biological Defense (Applied Research)* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2020 | FY 2021 | FY 2022 |
|---|---|---|---|
| Decrease due to change in program/project technical parameters. | | | |
| ***Title:*** 28) Lightweight Protective Garments<br><br>***Description:*** This effort supports the Percutaneous Protection Core Capability Area. Efforts will advance garment material and ensemble technologies with new capabilities using integrated garment designs and fabrication for thermal burden reduction, state-of-the-art threat protection technologies, and supporting test methodologies and methods that provide operationally relevant, comparable data on test garments.<br><br>***FY 2021 Plans:***<br>- Modify and validate Photographic Aerosol System Test (AST) protocol to incorporate female test participant and continued to improve Porton Man testing in support of the Uniform Integrated Protection Ensemble Family of Systems Program of Record.<br>- Transition improved protective garment test methodologies that provide greater validation of chemical biological protection, are repeatable and support testing under relevant conditions to the Uniform Integrated Protection Ensemble Family of Systems Program of Record.<br>- Transfer antimicrobial fabrics to test base and advance to BA3 in support of the Uniform Integrated Protection Ensemble Family of Systems Program of Record.<br><br>***FY 2021 to FY 2022 Increase/Decrease Statement:***<br>Program/project transitioned to Advanced Development. | 0.301 | 0.555 | - |
| ***Title:*** 29) Respiratory and Ocular Protection<br><br>***Description:*** Development and integration of novel filtration media into a lightweight, low-profile, and low-burden individual protective filter, which has enhanced performance against a broader range of challenges that include Chemical Warfare Agents (CWA), Biological Weapons Agents (BWA), and Toxic Industrial Chemicals (TICs). Development of respiratory protection and design for better interoperability to support longer range missions. This effort is being separated into two thrust areas starting in FY21: All Hazards & Respiratory Protection and Multifunction Materials for Protection. | 1.207 | - | - |
| ***Title:*** 30) All-Hazards & Respiratory Protection<br><br>***Description:*** This effort supports the Respiratory and Ocular Protection Core Capability Area. Efforts will improve chemical and biological agent protection while maintaining warfighter capability through integrated research on respirator, seams, closures, and new materials; perform early surveys for end-user jury input; frequent user operational evaluation; focus on closed circuit full spectrum respiratory protection.<br><br>***FY 2021 Plans:***<br>- Continue to explore trade space for next generation general purpose mask. | - | 3.324 | 1.380 |

| Exhibit R-2A, RDT&E Project Justification: PB 2022 Chemical and Biological Defense Program | | Date: May 2021 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 2 | **R-1 Program Element (Number/Name)**<br>PE 0602384BP / *CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)* | **Project (Number/Name)**<br>CB2 / *Chemical Biological Defense (Applied Research)* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2020 | FY 2021 | FY 2022 |
|---|---|---|---|
| - Continue development of systems that provide chemical biological respiratory protection technologies in support of tactical all hazard, full spectrum respiratory protection system.<br>- Complete system testing and transition cooling garment systems to Uniform Integrated Protection Ensemble Family of Systems Program of Record.<br>***FY 2022 Plans:***<br>- Transition lightweight protective garment for all hazards environments to Uniform Integrated Protection Ensemble Family of Systems Program of Record.<br>- Complete development of systems that provide chemical biological respiratory protection technologies in support of tactical all hazard, full spectrum respiratory protection system.<br>- Develop next generation respiratory protection technology in the form of a low-burden, non-contact powered respirator with novel filter designs that integrates with Warfighter technologies and reduces encumbrance.<br>***FY 2021 to FY 2022 Increase/Decrease Statement:***<br>Decrease due to change in program/project technical parameters. Decrease is due to transition of Tactical All Hazards Technologies (cooling garments and full spectrum respiratory protection). | | | |
| ***Title:*** 31) Multifunction Materials for Protection<br>***Description:*** This effort supports the Respiratory and Ocular Protection, Percutaneous Protection, Expeditionary Collective Protection, Materiel Contamination Mitigation, and Personnel Contamination Mitigation Core Capability Areas. Efforts will discover, develop and integrate novel, reactive/catalytic materials and scale material manufacturing with maximum sorption and reactivity, and characterize materials using state-of-the-art in operando and ambient pressure spectroscopies, for eventual integration into next generation decontaminants, coatings, filters, and protective garments that reactively decontaminate chemical warfare agents.<br>***FY 2021 Plans:***<br>- Continue to engineer reactive/catalytic nano-structure materials from basic research efforts for chemical agent destruction, to facilitate air purification enhancement.<br>- Continue to integrate engineered reactive/catalytic nano-structure materials into filters, decontaminants, and textiles to assess materials in an operationally-relevant environment for personnel decontamination.<br>***FY 2022 Plans:***<br>- Continue to engineer reactive/catalytic nano-structure materials from basic research efforts for chemical agent destruction, to facilitate air purification enhancement.<br>- Continue to integrate engineered reactive/catalytic nano-structure materials into filters, decontaminants, and textiles to assess materials in an operationally-relevant environment for personnel decontamination. | - | 3.461 | 5.677 |

| Exhibit R-2A, RDT&E Project Justification: PB 2022 Chemical and Biological Defense Program | | Date: May 2021 |
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| **Appropriation/Budget Activity**<br>0400 / 2 | **R-1 Program Element (Number/Name)**<br>PE 0602384BP / *CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)* | **Project (Number/Name)**<br>CB2 / *Chemical Biological Defense (Applied Research)* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2020 | FY 2021 | FY 2022 |
|---|---|---|---|
| - Develop self-decontaminating, reusable protective garments of composite textiles with a reactive barrier, improved protection, and reduced thermal burden/life-cycle costs for advancement to the BA3 level.<br><br>***FY 2021 to FY 2022 Increase/Decrease Statement:***<br>Increase due to change in program/project technical parameters. | | | |
| ***Title:*** 32) Personnel Contamination Mitigation<br><br>***Description:*** Develop new technologies to mitigate the risk associated with contaminated human remains and personal effects (materials) exposed to and contaminated by chemical agents by neutralizing and/or physically removing the residual chemical agents. This effort is transitioning to the Personnel Decontamination thrust area starting in FY21. | 1.365 | - | - |
| ***Title:*** 33) Personnel Decontamination<br><br>***Description:*** This effort supports the Personnel Contamination Mitigation Core Capability Area. Efforts will develop decontaminants for decontamination of unbroken skin with lower lifecycle costs and storage constraints and determination of time, efficacy and logistics burdens to warfighters for mass casualty decontamination. Decrease Warfighter burden in the event of a CWA exposure by identifying science and technology gaps in the mass personnel decontamination process as well as possible substitutions for current approved personnel decontamination formulations.<br><br>***FY 2021 Plans:***<br>- Continue evaluating polymer coatings as potential temporary or permanent military equipment coatings to decrease logistical burden of decontamination in support of CBRN Coatings, Coverings, and Protective Overlays Program of Record.<br>- Increase chemical agent resistance of current military coatings through development and testing of novel temporary coatings to reduce the spread of contamination and enable more facile decontamination of military assets.<br>- Continue to improve equipment coatings through bio-inspired surface treatments to repel agents of interest from current military equipment coatings.<br><br>***FY 2022 Plans:***<br>- Continue to develop and assess physical removal technologies for potential replacement of Reactive Skin Decontamination Lotion in support of the Next Generation Personnel Decontamination Program of Record.<br>- Continue to integrate new dry decontamination into a mitt form-factor and determine science and technology challenges within process and procedure improvements.<br>- Develop methodologies and procedures to for military working dog decontamination.<br><br>***FY 2021 to FY 2022 Increase/Decrease Statement:*** | - | 1.311 | 1.180 |

| Exhibit R-2A, RDT&E Project Justification: PB 2022 Chemical and Biological Defense Program | | Date: May 2021 |
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| B. Accomplishments/Planned Programs ($ in Millions) | FY 2020 | FY 2021 | FY 2022 |
|---|---|---|---|
| Minor change due to routine program adjustments. | | | |
| ***Title:*** 34) Expeditionary Collective Protection<br>***Description:*** Develop new technologies for soldiers to determine the remaining chemical vapor service life of their Chemical Warfare Agents (CWA) filters. This effort is transitioning to the Air Purification Enhancements thrust area starting in FY21. | 0.897 | - | - |
| ***Title:*** 35) Air Purification Enhancements<br>***Description:*** This effort supports the Expeditionary Collective Protection (CP) Core Capability Area. Existing CP systems have high life cycle costs driven by maintenance and limited service life. JSTO efforts will focus on optimizing and extending filter life to reduce lifecycle costs while maintaining or improving protection.<br>***FY 2021 Plans:***<br>- Identify new filter bed materials that are capable of reacting, sorbing, and neutralizing chemical and biological agents.<br>- Continue efforts for novel filtration against nontraditional agents and other emerging threats in ColPro and other large-scale filter systems and testing under relevant environmentally-relevant conditions in support of the Collective Protection Modernization Program of Record.<br>***FY 2022 Plans:***<br>- Continue integration of the full range of nontraditional agents, including other emerging threats into the air purification enhancement portfolio and testing under relevant environmentally-relevant conditions.<br>- Continue efforts for novel filtration against nontraditional agents and other emerging threats in ColPro and other large-scale filter systems in support of the Collective Protection Modernization Program of Record.<br>***FY 2021 to FY 2022 Increase/Decrease Statement:***<br>Decrease due to change in program/project technical parameters. | - | 0.982 | 0.393 |
| **Accomplishments/Planned Programs Subtotals** | 82.539 | 103.497 | 104.362 |

**C. Other Program Funding Summary ($ in Millions)**

| Line Item | FY 2020 | FY 2021 | FY 2022 Base | FY 2022 OCO | FY 2022 Total | FY 2023 | FY 2024 | FY 2025 | FY 2026 | Cost To Complete | Total Cost |
|---|---|---|---|---|---|---|---|---|---|---|---|
| • CB3: *Chemical Biological Defense (ATD)* | 26.426 | 27.448 | 27.146 | - | 27.146 | - | - | - | - | - | - |
| • ET3: *Emerging Threats (ATD)* | 0.000 | 0.000 | 6.000 | - | 6.000 | - | - | - | - | - | - |

**Remarks**

| Exhibit R-2A, RDT&E Project Justification: PB 2022 Chemical and Biological Defense Program | | Date: May 2021 |
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| **Appropriation/Budget Activity**<br>0400 / 2 | **R-1 Program Element (Number/Name)**<br>PE 0602384BP / *CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)* | **Project (Number/Name)**<br>CB2 / *Chemical Biological Defense (Applied Research)* |

**D. Acquisition Strategy**

N/A

| Exhibit R-2A, RDT&E Project Justification: PB 2022 Chemical and Biological Defense Program | | | Date: May 2021 |
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| Appropriation/Budget Activity<br>0400 / 2 | R-1 Program Element (Number/Name)<br>PE 0602384BP / *CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)* | Project (Number/Name)<br>NT2 / *Non-Traditional Agents Defense (Applied Research)* | |

| COST ($ in Millions) | Prior Years | FY 2020 | FY 2021 | FY 2022 Base | FY 2022 OCO | FY 2022 Total | FY 2023 | FY 2024 | FY 2025 | FY 2026 | Cost To Complete | Total Cost |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| NT2: *Non-Traditional Agents Defense (Applied Research)* | - | 49.222 | 0.000 | 0.000 | - | 0.000 | - | - | - | - | - | - |

**A. Mission Description and Budget Item Justification**

Project NT2 provides early applied research to enhance and develop defensive capabilities against Non-Traditional Agents (NTAs). This project focuses on expanding scientific knowledge required to develop defensive capabilities and to demonstrate fast and agile scientific responses to enhance or develop capabilities that address emerging threats. Efforts and studies conducted under this project address direction from the FDA to conduct specific post-New Drug Application (NDA)-approval efforts and studies (e.g. required studies, Post Marketing Commitments), and requirements from the joint service users. This project is a comprehensive and focused effort for developing NTA defense capabilities, coordinated with specific interagency partners for doctrine, equipment, and training for the Warfighter and civilian population for defense against NTAs.

Individual efforts in this project include:
- Support an integrated approach to counter emerging threats through innovative science and technology (S&T) solutions for detection, protection, decontamination, information systems and modeling and simulation, and medical countermeasures.
- Provides for the upgrade and modernization of Medical Chemical Defense countermeasures which include U.S. Food and Drug Administration (FDA) approved prophylactics, pre-treatments, and therapeutics and intend to protect and/or sustain the Joint Service Member in a toxic chemical threat environment.

Starting in FY21, a portion of the NTA lines have been merged into RDT&E Projects CB2, Chemical Biological Defense, and TM2, Techbase Medical Defense. The administrative change is intended to improve S&T budget agility and transition efficiency.

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2020 | FY 2021 | FY 2022 |
|---|---|---|---|
| ***Title:*** 1) Chemical Pretreatments and Prophylactics - Medical | 5.012 | - | - |
| ***Description:*** Develops pretreatments and prophylactics that provide protection against NTAs and emerging chemical threats. Prophylactic MCMs include catalytic and stoichiometric bioscavengers that rapidly bind and detoxify a broad spectrum of NTAs.<br><br>Transferred FY19 NT2 funds to NT3 in FY20/21 to support more advanced efforts such as the opioid MCMs and 2-PAM BBB delivery efforts. | | | |
| ***Title:*** 2) Chemical Therapeutics - Medical | 15.700 | - | - |
| ***Description:*** Investigates common mechanisms of agent injury. Physiological parameters and pathological assessments will be used to establish the general mode and mechanism(s) of toxicity to inform countermeasure development. Develops, assesses, evaluates, and validates therapeutics for treatment resulting from exposure to NTAs and emerging chemical threats. | | | |

| Exhibit R-2A, RDT&E Project Justification: PB 2022 Chemical and Biological Defense Program | | Date: May 2021 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 2 | **R-1 Program Element (Number/Name)**<br>PE 0602384BP / *CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)* | **Project (Number/Name)**<br>NT2 / *Non-Traditional Agents Defense (Applied Research)* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2020 | FY 2021 | FY 2022 |
|---|---|---|---|
| ***Title:*** 3) Expeditionary Collective Protection<br>***Description:*** Develop new technologies for soldiers to determine the remaining chemical vapor service life of their chemical warfare agent (CWA) filters. | 0.690 | - | - |
| ***Title:*** 4) Material Contamination Mitigation<br>***Description:*** Develop highly effective non-traditional or novel decontamination technologies that integrate with current procedures and support non-material improvements of the overall decontamination effort. | 0.692 | - | - |
| ***Title:*** 5) Modeling & Simulation<br>***Description:*** Provide modeling of NTA materials for hazard prediction. Develop NTA source term algorithms for predicting chemical hazards from intentionally functioning weapons, counter-proliferation scenarios (bomb on target), and missile intercept. Investigate NTA agent fate for secondary effects, environmental/atmospheric chemistry, atmospheric and waterborne transport and dispersion, human effects, model Validation and Verification (V&V), scaled testing, casualty estimation, and supporting data management. | 1.491 | - | - |
| ***Title:*** 6) Percutaneous Protection<br>***Description:*** Study and assessment of percutaneous protective technologies to include membrane and composite material ("novel materials"/"multifunctional materials"). | 0.973 | - | - |
| ***Title:*** 7) Personnel Contamination Mitigation<br>***Description:*** Develop new technologies to mitigate the risk associated with contaminated human remains and personal effects (materials) exposed to and contaminated by chemical agents by neutralizing and/or physically removing the residual chemical agents. | 0.444 | - | - |
| ***Title:*** 8) Respiratory and Ocular Protection<br>***Description:*** Development and analysis of design alternatives for chemical and biological air-purifying respirators that provide enhanced protection with lower physiological burden and improved interface with mission equipment. | 0.691 | - | - |
| ***Title:*** 9) Threat Agent Sciences<br>***Description:*** Provide critical agent characterization (chemical, physical and physiological/toxicological) data on current and emerging threat agents to prepare for surprise, enabling and informing development and testing of NTA defense technology (e.g., detection, decontamination, protection, and hazard assessment). This characterization of new threats informs decision makers | 23.529 | - | - |

| Exhibit R-2A, RDT&E Project Justification: PB 2022 Chemical and Biological Defense Program | | Date: May 2021 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 2 | **R-1 Program Element (Number/Name)**<br>PE 0602384BP / *CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)* | **Project (Number/Name)**<br>NT2 / *Non-Traditional Agents Defense (Applied Research)* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2020 | FY 2021 | FY 2022 |
|---|---|---|---|
| and development of Concept of Operations (CONOPs) and Tactics, Techniques and Procedures (TTP); it also provides the basis for countermeasure development and assessment. | | | |
| **Accomplishments/Planned Programs Subtotals** | 49.222 | - | - |

**C. Other Program Funding Summary ($ in Millions)**

| Line Item | FY 2020 | FY 2021 | FY 2022 Base | FY 2022 OCO | FY 2022 Total | FY 2023 | FY 2024 | FY 2025 | FY 2026 | Cost To Complete | Total Cost |
|---|---|---|---|---|---|---|---|---|---|---|---|
| • CB3: *Chemical Biological Defense (ATD)* | 26.426 | 27.448 | 27.146 | - | 27.146 | - | - | - | - | - | - |
| • ET3: *Emerging Threats (ATD)* | 0.000 | 0.000 | 6.000 | - | 6.000 | - | - | - | - | - | - |
| • NT3: *Non-Traditional Agents Defense (ATD)* | 28.344 | 15.308 | 18.396 | - | 18.396 | - | - | - | - | - | - |
| • TM3: *Techbase Medical Defense (ATD)* | 142.123 | 137.829 | 137.495 | - | 137.495 | - | - | - | - | - | - |

**Remarks**

**D. Acquisition Strategy**

N/A

| Exhibit R-2A, RDT&E Project Justification: PB 2022 Chemical and Biological Defense Program | | | Date: May 2021 |
|---|---|---|---|
| Appropriation/Budget Activity<br>0400 / 2 | R-1 Program Element (Number/Name)<br>PE 0602384BP / *CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)* | Project (Number/Name)<br>TM2 / *Techbase Medical Defense (Applied Research)* | |

| COST ($ in Millions) | Prior Years | FY 2020 | FY 2021 | FY 2022 Base | FY 2022 OCO | FY 2022 Total | FY 2023 | FY 2024 | FY 2025 | FY 2026 | Cost To Complete | Total Cost |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| TM2: *Techbase Medical Defense (Applied Research)* | - | 69.344 | 98.310 | 102.594 | - | 102.594 | - | - | - | - | - | - |

**A. Mission Description and Budget Item Justification**

Project TM2 provides for applied research for innovative technology approaches to advance medical systems designed to rapidly identify, diagnose, prevent, and treat disease due to exposure to chemical and biological threat agents. Project NT2, Techbase Non-Traditional Agents Defense, will merge into this Project starting in FY21.

Individual efforts in this project include:
- Core science efforts in Medical Chemical, Medical Biological, Diagnostics, and Medical Countermeasures.
- Supports applied research for the investigation of new medical countermeasures to include prophylaxes, pretreatments, antidotes, skin decontaminants, and therapeutic drugs against identified and emerging biological and chemical warfare agents.
- Medical Science and Technology (S&T) efforts in this Budget Activity refine promising medical initiatives identified in Budget Activity 1, resulting in the development of countermeasures to protect against and treat the effects of exposure to chemical and biological (CB) agents.
- Diagnostic research focuses on providing high quality data closer to the point-of-need comprising device innovation, panels of biomarkers driven by bioinformatics, and epidemiological modeling tools.

FY21-22 reorganizes, renames legacy Bullet titles and introduces new Bullets (Thrust Areas). These new "Thrust" titles are in line with the CBDP Core Capability Areas and intended to provide more detail and traceability from the S&T program to advanced development.

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2020 | FY 2021 | FY 2022 |
|---|---|---|---|
| ***Title:*** 1) Medical Diagnostics | 12.843 | - | - |
| ***Description:*** Investigate medical diagnostics ubiquitous and comprehensive against chemical and biological threats (including NTAs, pharmaceutical-based agents, and toxins) by advancing diagnostic innovations; investigating emerging technologies; ensuring medical diagnostics rapid adaptation to emerging threats; harvesting and synergizing the immense volume of diagnostic data; and aligning medical diagnostics capabilities with the FDA pipeline and larger commercial supply chain. This effort is being separated into three thrust areas starting in FY21: Chemical Diagnostics, Diagnostic Building Blocks, and Emerging Threats. | | | |
| ***Title:*** 2) Chemical Diagnostics | - | 1.770 | 1.554 |
| ***Description:*** Develop diagnostics for exposure to traditional and nontraditional chemical warfare agents (CWAs) and pharmaceutical based agents (PBAs). Early identification and diagnosis is key to appropriate medical countermeasure (MCM) treatment and enhances force protection and lethality. | | | |
| ***FY 2021 Plans:*** | | | |

| Exhibit R-2A, RDT&E Project Justification: PB 2022 Chemical and Biological Defense Program | | Date: May 2021 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 2 | **R-1 Program Element (Number/Name)**<br>PE 0602384BP / *CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)* | **Project (Number/Name)**<br>TM2 / *Techbase Medical Defense (Applied Research)* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2020 | FY 2021 | FY 2022 |
|---|---|---|---|
| - Complete the development of the Chemical Diagnostics (CHEMDX) system and transition the device to the Joint Product Executive Office (JPEO) Program of Record (POR) for advanced development and FDA clearance.<br>- Continue the development of new and optimized lab-based assays, field forward sampling, and in vitro diagnostic (IVD) technologies to verify human exposures to organophosphates (OP) and mustard (HD).<br>- Continue the development of strategies to address portable ultra-low detection of opioids.<br>***FY 2022 Plans:***<br>- Initiate the development to adapt the CHEMDX platform to simultaneously measure organophosphate nerve agent and fentanyl exposure to rapidly inform whether an individual has been exposed to a high probability incapacitant.<br>- Complete the development of new and optimized lab-based assays, field forward sampling, and IVD technologies to verify human exposures to OP and HD.<br>- Continue the development of strategies to address portable ultra-low detection of opioids.<br>***FY 2021 to FY 2022 Increase/Decrease Statement:***<br>Minor change due to routine program adjustments. | | | |
| ***Title:*** 3) Diagnostic Building Blocks<br>***Description:*** The Diagnostic Building Blocks thrust area lays a foundation for the entire diagnostics portfolio by exploiting areas such as machine learning (ML), synthetic biology and chemistry to develop novel and rapid diagnostic tests for utilization in the event of an outbreak of an unknown threat.<br>***FY 2021 Plans:***<br>- Continue the development of protocols for generating synthetic molecular binding agents (SYMBAs) that are sensitive and specific, and can be applied to various diagnostic platforms, supporting open-architecture capabilities.<br>- Continue the research and development of clustered regularly interspaced short palindromic repeat (CRISPR) based solutions for field diagnostics that will provide an ultra-sensitive, cost-effective, and accurate medical diagnostic solution for the Warfighter against unknown biological threats.<br>***FY 2022 Plans:***<br>- Complete the development of protocols for generating SYMBAs that are sensitive and specific and can be applied to various diagnostic platforms, supporting open-architecture capabilities<br>***FY 2021 to FY 2022 Increase/Decrease Statement:***<br>Decrease due to change in program/project technical parameters. | - | 5.644 | 4.446 |
| ***Title:*** 4) Emerging Threats | - | 7.439 | 4.110 |

| Exhibit R-2A, RDT&E Project Justification: PB 2022 Chemical and Biological Defense Program | | Date: May 2021 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 2 | **R-1 Program Element (Number/Name)**<br>PE 0602384BP / *CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)* | **Project (Number/Name)**<br>TM2 / *Techbase Medical Defense (Applied Research)* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2020 | FY 2021 | FY 2022 |
|---|---|---|---|
| ***Description:*** The Emerging Threats thrust area pushes beyond the boundaries of the traditional threat list in the field of diagnostics to better prepare for surprise by leveraging novel approaches to classify a threat from an unknown sample.<br><br>***FY 2021 Plans:***<br>- Continue research characterizing antimicrobial resistant (AMR)and antimicrobial susceptibility testing (AST) mechanisms in Burkholderia pseudomallei.<br>- Continue research into an improved diagnostic development pipeline for hard to detect pathogens.<br>- Continue the development of a comprehensive reference guide that will enable evidence based decision processes that drive the development of current and future diagnostic technologies.<br>- Continue evaluation efforts for adapting an FDA approved biomarker platform for diagnosis of human TBI to a platform for diagnosis of brain injury resulting from the encephalitic alphaviruses.<br>- Initiate efforts on several complementary approaches to address challenges in toxin diagnosis at the point of care (POC).<br>- Initiate the development of a universal blood sample preparation platform to be compatible with several diagnostic systems.<br>***FY 2022 Plans:***<br>- Complete research characterizing AMR and AST mechanisms in Burkholderia pseudomallei.<br>- Complete and validate an improved diagnostic development pipeline for hard to detect pathogens and transition to JPEO.<br>- Complete the development of a comprehensive reference guide that will enable evidence based decision processes that drive the development of current and future diagnostic technologies and transition to JPEO.<br>- Complete evaluation efforts for adapting an FDA approved biomarker platform for diagnosis of human TBI to a platform for diagnosis of brain injury resulting from the encephalitic alphaviruses.<br>- Continue efforts on several complementary approaches to address challenges in toxin diagnosis at the POC.<br>- Continue the development of a universal blood sample preparation platform to be compatible with several diagnostic systems.<br>***FY 2021 to FY 2022 Increase/Decrease Statement:***<br>Decrease due to change in program/project technical parameters. | | | |
| ***Title:*** 5) Bacterial/Viral/Toxins/ Broad Spectrum Prophylaxis | 21.071 | 26.029 | 29.560 |
| ***Description:*** Provide the warfighter protection against biothreat agents through the administration of prophylaxis against known bacterial, viral and toxin threats of interest and emerging infectious threats. Use novel technology and methods to support development of vaccine candidates. Conduct studies to determine potential immune interference between lead vaccine candidates, the effect of alternative vaccine delivery methods, and thermo-stabilization technologies on the efficacy of lead vaccine candidates. Identify correlates of protection in humans, and predict the success of lead vaccine candidates in humans.<br><br>***FY 2021 Plans:*** | | | |

| Exhibit R-2A, RDT&E Project Justification: PB 2022 Chemical and Biological Defense Program | | Date: May 2021 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 2 | **R-1 Program Element (Number/Name)**<br>PE 0602384BP / *CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)* | **Project (Number/Name)**<br>TM2 / *Techbase Medical Defense (Applied Research)* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2020 | FY 2021 | FY 2022 |
|---|---|---|---|
| Bacterial:<br>- Continue evaluation of Q fever vaccines based on selected T and B cell antigens.<br>- Continue development of nanoparticle tularemia vaccine.<br>- Continue nonclinical development of Burkholderia vaccines.<br>- Evaluate protective efficacy of Anthrax vaccines against novel Bacillus anthracis strains.<br>- Initiate development of Burkholderia monoclonal antibodies.<br>- Continue evaluation of Burkholderia and Q Fever vaccines in the biomimetic Modular Immune In-vitro Construct (MIMIC) system.<br>- Continue to sustain the Human Specimen Archive at United States Army Medical Research Institute of Infectious Diseases (USAMRIID).<br><br>Viral:<br>- Continue development of inactivated alphavirus vaccine.<br>- Continue establishment of humoral correlates of protection against Ebola virus.<br>- Continue biomarker discovery and host pathway/pathogen interactions important for protection against hemorrhagic fever viruses.<br>- Continue improvements to immunogenicity, efficacy and manufacturing of Venezuelan Equine Encephalitis Virus (VEEV) DNA vaccine.<br>- Continue development of multiplexed VEEV infection biomarker assay and qualification/validation of VEEV immune assays for clinical and pivotal animal studies.<br>- Continue development of DNA vaccine against Marburg Virus.<br>- Continue to evaluate alternative delivery devices for DNA vaccines in large animal studies.<br><br>Toxins:<br>- Continue development of well-defined animal models for medical countermeasure development against aerosolized biological toxins including marine toxins.<br>- Continue evaluation of toxins and antitoxin prophylaxis in animal models.<br>- Continue development of prototype mAb based drugs.<br>- Initiate development of functional assays to determine biological activity for various toxins.<br><br>Broad Spectrum:<br>- Continue nonclinical evaluation of hybrid Staphylococcus enterotoxin and arenavirus antigen vaccines in in vitro assays and small animal models.<br>- Continue to qualify/validate MIMIC for use in evaluation of pulmonary responses to biodefense vaccines. | | | |

| Exhibit R-2A, RDT&E Project Justification: PB 2022 Chemical and Biological Defense Program | | Date: May 2021 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 2 | **R-1 Program Element (Number/Name)**<br>PE 0602384BP / *CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)* | **Project (Number/Name)**<br>TM2 / *Techbase Medical Defense (Applied Research)* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2020 | FY 2021 | FY 2022 |
|---|---|---|---|
| - Initiate development of broad spectrum, novel antitoxin technologies including exploring the use of cell membrane coated nanosponges.<br>- Initiate novel pan virus nanosponge platform development, explore additional applications of nanosponge technology to include toxins and bacteria.<br><br>***FY 2022 Plans:***<br>Bacterial:<br>- Complete the non-clinical animal studies for two back-up Burkholderia vaccine candidates. Candidates will proceed in development under BA3 funding if results indicated candidates are efficacious, otherwise, efforts will be terminated.<br>- Continue development of Burkholderia monoclonal antibodies.<br>- Continue non-clinical animal immunogenicity and efficacy studies for a Tularemia subunit.<br>- Continue efforts in enabling science and NHP efficacy model development for Q fever.<br>- Continue Q Fever vaccine prototype testing and candidate down selection.<br>- Continue to evaluate protective efficacy of Anthrax vaccines against novel Bacillus anthracis strains.<br><br>Viral:<br>- Initiate non-clinical animal studies for the Inactivated Western, Eastern, and Venezuelan Equine Encephalitis (WEVEE) vaccine candidate.<br>- Initiate non-clinical animal studies for the Trivalent Western Equine Encephalitis and Venezuelan Equine Encephalitis (WEEVEE) DNA vaccine.<br>- Complete initial development of alphavirus mAbs against VEEV, EEEV, and WEEV, epitope identification and mAb generation. Project will continue utilizing BA3 funding.<br>- Conduct nonclinical safety and efficacy studies for the Marburg Virus (MARV) DNA vaccine.<br>- Down-select between alternative delivery devices for DNA vaccine delivery.<br><br>Toxins:<br>- Conduct epitope identification and mAbs generation against several marine toxins.<br>- Continue to develop novel antitoxin technologies including exploring the use of cell membrane coated nanosponges.<br>- Continue evaluation of toxins and antitoxin prophylaxis in animal models.<br>- Continue to develop functional assays to determine biological activity for various toxins.<br><br>Broad Spectrum:<br>- Continue novel pan virus nanosponge platform development to address emerging threats, explore additional applications of nanosponge technology to include emerging toxins and bacterial threats. | | | |

| Exhibit R-2A, RDT&E Project Justification: PB 2022 Chemical and Biological Defense Program | | Date: May 2021 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 2 | **R-1 Program Element (Number/Name)**<br>PE 0602384BP / *CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)* | **Project (Number/Name)**<br>TM2 / *Techbase Medical Defense (Applied Research)* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2020 | FY 2021 | FY 2022 |
|---|---|---|---|
| - Explore additional strategies and platforms for broad spectrum protection to address protection against emerging threats.<br>- Evaluation of next generation adjuvants for use in biodefense vaccines.<br>- Initiate nonclinical evaluation of multivalent vaccine against arenaviruses.<br>- Continue to qualify/validate MIMIC for use in evaluation of pulmonary responses to biodefense vaccines.<br>***FY 2021 to FY 2022 Increase/Decrease Statement:***<br>Increase due to change in program/project technical parameters. | | | |
| ***Title:*** 6) Chemical Therapeutics<br>***Description:*** Focuses on therapeutic strategies to effectively minimize injuries resulting from exposure to CWAs. This effort involves the development of neuroprotectants, anticonvulsants, improved therapies for enzyme reactivation, and investigation of alternate pathways leading to treatment. This effort also includes discovery and development of therapeutic strategies to treat dermal, ocular and respiratory injuries of CWAs. Efforts in this area are designed to develop potential candidates that will ultimately be submitted for Food and Drug Administration (FDA) licensure or to identify previously licensed products for new uses in the treatment of chemical warfare casualties. This effort is being separated into four thrust areas starting in FY21: Chemical Reactive Ocular Wound and Dermal Therapeutics (CROWD), Enabling Science, Pharmaceutical Based Agents (PBA), and Reactivators of AChE as Therapeutics (ReACT). | 10.138 | - | - |
| ***Title:*** 7) Chemical Reactive Ocular Wound and Dermal Therapeutics (CROWD)<br>***Description:*** Focuses on therapeutic strategies to effectively treat CWA contamination on wounds, eyes, and large areas of intact skin. This effort involves the development of products capable of removing or neutralizing CWAs from those routes of exposure, to decrease the toxic load of agent and allow optimal effectiveness of other systemic therapeutics.<br>***FY 2021 Plans:***<br>- Proof of concept test of candidate decontamination products for capability to decontaminate CWAs from wounds.<br>***FY 2022 Plans:***<br>- Determination of dosing strategies for use of candidate products in traumatic wounds.<br>- Perform advanced preclinical studies to validate safety and efficacy in support of clinical trials.<br>- Assessment of candidate product readiness for advanced development.<br>- Continue refinement of manufacturing and stability.<br>***FY 2021 to FY 2022 Increase/Decrease Statement:***<br>Increase due to change in program/project technical parameters. | - | 3.126 | 6.679 |
| ***Title:*** 8) Enabling Science | - | 10.002 | 11.148 |

| Exhibit R-2A, RDT&E Project Justification: PB 2022 Chemical and Biological Defense Program | | Date: May 2021 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 2 | **R-1 Program Element (Number/Name)**<br>PE 0602384BP / *CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)* | **Project (Number/Name)**<br>TM2 / *Techbase Medical Defense (Applied Research)* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2020 | FY 2021 | FY 2022 |
|---|---|---|---|
| ***Description:*** Enables the accelerated development and deployment of therapeutics and prophylactics to the warfighter for protection against CWAs by leveraging technological advances to more efficiently assess the safety and efficacy of new candidates for IND submission.<br>Efforts in this area include the development of anticholinergics, anticonvulsants, neuroprotectants, and delivery technologies to deliver therapeutics across the blood brain barrier (BBB). Efforts in this area establish therapeutic candidate libraries and pipelines using high throughput screening, artificial intelligence based drug design, and predictive toxicology.<br><br>***FY 2021 Plans:***<br>- Continue development of therapeutic candidate pipelines to treat CWAs using high throughput screening and AI-based predictive ADME/T<br>- Continue to maintain databases of both screening and ADME/T data for drug candidates.<br>- Complete in vitro ultra high throughput screening of library compounds for use as anticholinergics.<br>- Down select generated chemical libraries to the most promising therapeutic candidates for follow on safety and efficacy assessments<br>- Integrate Chemoinformatics System's ADME/T prediction tools with high throughput screening data into a high throughput screening database to support hit prioritization and identification of lead therapeutic candidates.<br>- Incorporate and further develop AI/machine learning methods to optimize drug design.<br>- Continue development of technologies for 2-PAM delivery across the BBB.<br><br>***FY 2022 Plans:***<br>- Employ AI-based computational toxicology and drug design system incorporating machine learning algorithms to streamline drug design.<br>- Continue to maintain databases of both high throughput screening and ADME/T data for drug candidates.<br>- Continue to perform select animal and safety studies for lead therapeutic candidates, including anticholinergics, for treatment of CWAs.<br>- Continue to develop encapsulation and shuttle technologies that will deliver the 2-PAM payload across the BBB.<br>- Continue to support the therapeutic candidate pipeline.<br>- Perform follow on in vitro and in vivo safety and efficacy studies to support the down selection of high throughput screening hits to leads.<br><br>***FY 2021 to FY 2022 Increase/Decrease Statement:***<br>Increase due to change in program/project technical parameters. | | | |
| ***Title:*** 9) Pharmaceutical Based Agents (PBAs) | - | 6.564 | 7.390 |

| Exhibit R-2A, RDT&E Project Justification: PB 2022 Chemical and Biological Defense Program | | Date: May 2021 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 2 | **R-1 Program Element (Number/Name)**<br>PE 0602384BP / *CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)* | **Project (Number/Name)**<br>TM2 / *Techbase Medical Defense (Applied Research)* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2020 | FY 2021 | FY 2022 |
|---|---|---|---|
| ***Description:*** Focuses on therapeutic strategies to effectively minimize injuries resulting from exposure to Pharmaceutical Based Agents (PBAs). This effort involves the evaluation FDA approved therapeutics for operational use, as well as generation of novel drug products to enhance level of protection and/or operational utility for the Warfighter. Efforts in this area are designed to develop drug candidates that will ultimately be submitted for Food and Drug Administration (FDA) licensure or to identify previously licensed products for new uses in the treatment of chemical warfare casualties.<br><br>***FY 2021 Plans:***<br>- Continue development of novel opioid therapeutics which will allow current pain management doctrine.<br>- Continue operational assessment of FDA approved drug products to inform MCM timing and sequence in the event of a known or unknown chemical exposure.<br>- Assess drug products for use against other priority PBA emerging threats (e.g., non-opioids).<br><br>***FY 2022 Plans:***<br>- Continue development of novel opioid therapeutics which will allow current pain management doctrine.<br>- Continue operational assessment of FDA approved drug products to inform MCM timing and sequence in the event of a known or unknown chemical exposure.<br>- Continue to assess drug products for use against other priority PBA emerging threats (e.g., non-opioids)<br><br>***FY 2021 to FY 2022 Increase/Decrease Statement:***<br>Increase due to change in program/project technical parameters. | | | |
| ***Title:*** 10) Reactivators of AChE as Therapeutics (ReACT)<br><br>***Description:*** Focuses on therapeutic strategies to effectively minimize injuries resulting from exposure to CWAs. This effort involves the development of improved therapies for enzyme reactivation. Efforts in this area are designed to develop potential candidates that will ultimately be submitted for Food and Drug Administration (FDA) licensure or to identify previously licensed products for new uses in the treatment of chemical warfare casualties.<br><br>***FY 2021 Plans:***<br>- Test the efficacy of candidate resurrectors of inhibited acetylcholinesterase in vivo in animal models.<br>- Continue to develop the most promising broad spectrum therapeutic candidates by using in vitro efficacy data from generated chemical libraries to inform iterative QSAR studies.<br>- Continue animal studies to support regulatory submission of candidate therapeutics for treatment of the toxic effects of selected, priority NTAs.<br>- Continue drug formulation efforts for MCMs with a longer shelf-life and with feasibility of an auto-injector containing material and chemical composition. | - | 7.501 | 5.262 |

| Exhibit R-2A, RDT&E Project Justification: PB 2022 Chemical and Biological Defense Program | | Date: May 2021 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 2 | **R-1 Program Element (Number/Name)**<br>PE 0602384BP / *CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)* | **Project (Number/Name)**<br>TM2 / *Techbase Medical Defense (Applied Research)* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2020 | FY 2021 | FY 2022 |
|---|---|---|---|
| - Continue validation and characterization of therapeutics for an improved broad spectrum reactivator<br>- Continue development of current and screening for novel broad spectrum cholinesterase reactivators that are effective in the brain.<br><br>***FY 2022 Plans:***<br>- Test the safety and efficacy of candidate resurrectors of inhibited acetylcholinesterase in vivo in animal models.<br>- Down select generated chemical libraries to the most promising broad spectrum therapeutic candidates for follow on safety and efficacy assessments.<br>- Continue drug formulation efforts for MCMs with a longer shelf-life and with feasibility of an auto-injector containing material and chemical composition.<br>- Continue development of current and screening for novel broad spectrum cholinesterase reactivators that are effective in the brain.<br><br>***FY 2021 to FY 2022 Increase/Decrease Statement:***<br>Decrease due to change in program/project technical parameters. | | | |
| ***Title:*** 11) Pretreatments and Prophylactics, Nerve Agents<br><br>***Description:*** Develop pretreatments and prophylactics that provide protection against chemical warfare agents, including organophosphorus nerve agents (OPNA), such as stoichiometric and catalytic scavengers and other entities that rapidly bind and detoxify a broad spectrum of agents.<br><br>***FY 2021 Plans:***<br>- Continue efforts to develop catalytic enzymes for use against selected, priority NTAs.<br>- Continue expanded pre-clinical studies of lead catalytic scavengers to support future investigative new drug (IND) filing.<br>- Continue efforts to develop capability for rapid development of medical countermeasures.<br>- Continue efforts to explore and further develop novel non-enzyme nerve agent prophylaxis.<br>- Continue new approaches to identify pretreatment and prophylaxis against multiple classes of NTAs and emerging chemical threats.<br><br>***FY 2022 Plans:***<br>- Continue efforts to develop catalytic enzymes for use against selected, priority NTAs.<br>- Continue expanded pre-clinical studies of lead catalytic scavengers to support future investigative new drug (IND) filing.<br>- Continue efforts to develop capability for rapid development of medical countermeasures.<br>- Continue efforts to explore and further develop novel non-enzyme nerve agent prophylaxis. | 0.537 | 4.063 | 3.282 |

| Exhibit R-2A, RDT&E Project Justification: PB 2022 Chemical and Biological Defense Program | | Date: May 2021 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 2 | **R-1 Program Element (Number/Name)**<br>PE 0602384BP / *CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)* | **Project (Number/Name)**<br>TM2 / *Techbase Medical Defense (Applied Research)* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2020 | FY 2021 | FY 2022 |
|---|---|---|---|
| - Continue new approaches to identify pretreatment and prophylaxis against multiple classes of NTAs and emerging chemical threats.<br><br>***FY 2021 to FY 2022 Increase/Decrease Statement:***<br>Decrease due to change in program/project technical parameters. | | | |
| ***Title:*** 12) Bacterial Therapeutics<br><br>***Description:*** Discover and develop therapeutic countermeasures to mitigate the effects of known and emerging bacterial threats to the warfighter.<br><br>***FY 2021 Plans:***<br>- Continue the discovery and advancement of novel, non-traditional (antimicrobial peptides, immunomodulators, host-directed therapies), as well as traditional, strategies to identify lead therapeutic candidates to treat bacterial infections.<br>- Continue discovery of antibody and derivatives to treat intracellular bacterial infection.<br>- Develop novel formulations of existing antibiotics to overcome antimicrobial resistance, improve pharmacokinetic parameters, dose-sparing and to enhance antimicrobial killing.<br><br>***FY 2022 Plans:***<br>- Continue efforts to discover and develop traditional (small molecule inhibitors) and non-traditional (phage therapies, antimicrobial peptides, immunomodulators, and host-directed therapies) therapeutic candidates to existing and emerging bacterial threats.<br>- Complete the development of formulations for existing antibiotic therapies that increase efficacy against bacterial pathogens and initiate proof of concept animal studies.<br>- Continue small animal proof of concept testing to identify novel/nontraditional therapies against all pathogens.<br><br>***FY 2021 to FY 2022 Increase/Decrease Statement:***<br>Increase due to change in program/project technical parameters. | 12.966 | 10.915 | 14.456 |
| ***Title:*** 13) Viral Therapeutics<br><br>***Description:*** Discover and develop therapeutic countermeasures to mitigate the effects of known and emerging viral threats to the warfighter.<br><br>***FY 2021 Plans:***<br>- Continue screening, evaluation and development of novel and repurposed, broad-spectrum small molecule inhibitors and biologics effective against viral infections in vitro and in vivo.<br>- Invest in identification of new pathways as antiviral drug targets.<br>- Continue development of animal models for evaluation of therapeutic countermeasures. | 11.465 | 15.006 | 14.457 |

| Exhibit R-2A, RDT&E Project Justification: PB 2022 Chemical and Biological Defense Program | | Date: May 2021 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 2 | **R-1 Program Element (Number/Name)**<br>PE 0602384BP / *CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)* | **Project (Number/Name)**<br>TM2 / *Techbase Medical Defense (Applied Research)* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2020 | FY 2021 | FY 2022 |
|---|---|---|---|
| - Explore target pathway analysis in mice and NHP to interrogate new potential targets for drug intervention.<br>***FY 2022 Plans:***<br>- Continuation of testing and development of biologics and small molecules targeting viral threats.<br>- Continuation of the discovery and down-selection of additional broad-spectrum, direct-acting and host-directed antivirals<br>- Initiate new investments in the discovery and down-selection of additional broad-spectrum, direct-acting and host-directed antiviral candidates for existing and emerging threats.<br>***FY 2021 to FY 2022 Increase/Decrease Statement:***<br>Minor change due to routine program adjustments. | | | |
| ***Title:*** 14) Toxin Therapeutics<br>***Description:*** Discover and develop therapeutic countermeasures to protect the warfighter against biotoxin threats.<br>***FY 2021 Plans:***<br>- Evaluate broad-spectrum, small molecule compounds and biologics for efficacy in the treatment and recovery from intoxication by BoNT.<br>- Evaluate swine as a large animal model for BoNT.<br>***FY 2022 Plans:***<br>- Continue evaluation of broad-spectrum, small molecule compounds and biologics for efficacy in the treatment and recovery from intoxication by BoNT.<br>***FY 2021 to FY 2022 Increase/Decrease Statement:***<br>Minor change due to routine program adjustments. | 0.324 | 0.251 | 0.250 |
| **Accomplishments/Planned Programs Subtotals** | 69.344 | 98.310 | 102.594 |

**C. Other Program Funding Summary ($ in Millions)**

| Line Item | FY 2020 | FY 2021 | FY 2022 Base | FY 2022 OCO | FY 2022 Total | FY 2023 | FY 2024 | FY 2025 | FY 2026 | Cost To Complete | Total Cost |
|---|---|---|---|---|---|---|---|---|---|---|---|
| • ET3: *Emerging Threats (ATD)* | 0.000 | 0.000 | 6.000 | - | 6.000 | - | - | - | - | - | - |
| • TM3: *Techbase Medical Defense (ATD)* | 142.123 | 137.829 | 137.495 | - | 137.495 | - | - | - | - | - | - |
| • MB4: *Medical Biological Defense (ACD&P)* | 41.997 | 47.727 | 47.351 | - | 47.351 | - | - | - | - | - | - |

| Exhibit R-2A, RDT&E Project Justification: PB 2022 Chemical and Biological Defense Program | | | Date: May 2021 |
|---|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 2 | **R-1 Program Element (Number/Name)**<br>PE 0602384BP / *CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)* | **Project (Number/Name)**<br>TM2 / *Techbase Medical Defense (Applied Research)* | |

**C. Other Program Funding Summary ($ in Millions)**

| Line Item | FY 2020 | FY 2021 | FY 2022 Base | FY 2022 OCO | FY 2022 Total | FY 2023 | FY 2024 | FY 2025 | FY 2026 | Cost To Complete | Total Cost |
|---|---|---|---|---|---|---|---|---|---|---|---|
| • MB5: *Medical Biological Defense (SDD)* | 170.345 | 117.956 | 137.348 | - | 137.348 | - | - | - | - | - | - |
| • MC5: *Medical Chemical Defense (SDD)* | 55.269 | 54.392 | 50.362 | - | 50.362 | - | - | - | - | - | - |
| • MB7: *Medical Biological Defense (Op Sys Dev)* | 2.663 | 2.308 | 3.833 | - | 3.833 | - | - | - | - | - | - |
| • MC7: *Medical Chemical Defense (Op Sys Dev)* | 1.222 | 1.817 | 1.336 | - | 1.336 | - | - | - | - | - | - |

**Remarks**

**D. Acquisition Strategy**

N/A