| Exhibit R-2, RDT&E Budget Item Justification: PB 2014 Defense Health Program | | | | | | | | | | | DATE: March 2013 | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | | | | | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | | | | | | | |
| **COST ($ in Millions)** | **All Prior Years** | **FY 2012** | **FY 2013#** | **FY 2014 Base** | **FY 2014 OCO ##** | **FY 2014 Total** | **FY 2015** | **FY 2016** | **FY 2017** | **FY 2018** | **Cost To Complete** | **Total Cost** |
| Total Program Element | - | 713.880 | 239.110 | 290.852 | - | 290.852 | 298.948 | 300.714 | 301.475 | 304.782 | Continuing | Continuing |
| 300A: *CSI - Congressional Special Interests* | - | 540.100 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |
| 238C: *Enroute Care Research & Development (Budgeted) (AF)* | - | 3.261 | 6.000 | 4.800 | - | 4.800 | 4.500 | 4.200 | 4.400 | 4.479 | Continuing | Continuing |
| 243A: *Medical Development (Lab Support) (Navy)* | - | 33.555 | 35.453 | 37.434 | - | 37.434 | 38.198 | 39.558 | 40.222 | 40.942 | Continuing | Continuing |
| 284B: *USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (Budgeted) (AF)* | - | 2.421 | 4.400 | 3.800 | - | 3.800 | 3.800 | 5.700 | 5.871 | 5.977 | Continuing | Continuing |
| 285A: *Operational Medicine Research & Development (Budgeted) (AF)* | - | 8.005 | 5.267 | 5.049 | - | 5.049 | 3.965 | 3.376 | 3.277 | 3.336 | Continuing | Continuing |
| 307B: *Force Health Protection, Advanced Diagnostics/ Therapeutics Research & Development (Budgeted) (AF)* | - | 14.335 | 12.120 | 15.796 | - | 15.796 | 16.648 | 17.852 | 18.991 | 19.333 | Continuing | Continuing |
| 308B: *Expeditionary Medicine Research & Development (Budgeted) (AF)* | - | 2.796 | 5.736 | 4.906 | - | 4.906 | 6.229 | 5.271 | 4.474 | 4.554 | Continuing | Continuing |
| 309A: *Regenerative Medicine (USUHS)* | - | 6.877 | 7.365 | 7.504 | - | 7.504 | 7.657 | 7.929 | 8.062 | 8.207 | Continuing | Continuing |
| 373A: *GDF - Medical Technology Development* | - | 48.595 | 107.248 | 150.166 | - | 150.166 | 161.729 | 161.320 | 160.683 | 163.575 | Continuing | Continuing |
| 378A: *CoE-Breast Cancer Center of Excellence (Army)* | - | 9.722 | 10.458 | 10.636 | - | 10.636 | 10.830 | 11.229 | 11.418 | 11.624 | Continuing | Continuing |

| Exhibit R-2, RDT&E Budget Item Justification: PB 2014 Defense Health Program | | | | | | | | | | | DATE: March 2013 | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | | | | | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | | | | | | | |
| 379A: *CoE-Gynecological Cancer Center of Excellence (Army)* | - | 8.494 | 9.138 | 9.293 | - | 9.293 | 9.463 | 9.811 | 9.977 | 10.157 | Continuing | Continuing |
| 381A: *CoE-Integrative Cardiac Health Care Center of Excellence (Army)* | - | 3.584 | 3.857 | 3.921 | - | 3.921 | 3.993 | 4.141 | 4.210 | 4.285 | Continuing | Continuing |
| 382A: *CoE-Pain Center of Excellence (Army)* | - | 2.715 | 2.921 | 2.971 | - | 2.971 | 3.025 | 3.137 | 3.190 | 3.247 | Continuing | Continuing |
| 383A: *CoE-Prostate Cancer Center of Excellence (USUHS)* | - | 7.164 | 7.978 | 8.294 | - | 8.294 | 8.634 | 8.943 | 9.093 | 9.256 | Continuing | Continuing |
| 398A: *CoE-Neuroscience Center of Excellence (USUHS)* | - | 1.822 | 1.948 | 1.981 | - | 1.981 | 2.017 | 2.053 | 2.088 | 2.126 | Continuing | Continuing |
| 429A: *Hard Body Armor Testing (Army)* | - | 0.813 | 0.607 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |
| 431A: *Underbody Blast Testing (Army)* | - | 14.544 | 13.142 | 11.614 | - | 11.614 | 5.353 | 2.977 | 2.077 | 0.000 | Continuing | Continuing |
| 448A: *Military HIV Research Program (Army)* | - | 0.000 | 0.000 | 7.111 | - | 7.111 | 7.216 | 7.321 | 7.445 | 7.579 | Continuing | Continuing |
| 830A: *Deployed Warfighter Protection (Army)* | - | 5.077 | 5.472 | 5.576 | - | 5.576 | 5.691 | 5.896 | 5.997 | 6.105 | Continuing | Continuing |

[#] FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

[##] The FY 2014 OCO Request will be submitted at a later date

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

Guidance for Development of the Force - Medical Technology Development provides funds for promising candidate solutions that are selected for initial safety and effectiveness testing in animal studies and/or small scale human clinical trials regulated by the US Food and Drug Administration prior to licensing for human use. Research in this PE is designed to address the following: Secretary of Defense areas of interest regarding Wounded Warriors, capabilities identified through the Joint Capabilities Integration and Development System, and the strategy and initiatives described in the Quadrennial Defense Review. Program development and execution is peer-reviewed and fully coordinated with all of the Military Services, appropriate Defense Agencies or Activities and other federal agencies, to include the Department of Veterans Affairs, the Department of Health and Human Services, and the Department of Homeland Security. This coordination occurs through the planning and execution activities of the Joint Program Committees (JPCs), established for the Defense Health Program, Research Development Test and Evaluation (RDT&E) funding. Research supported by this PE includes polytrauma and blast injury, diagnosis and treatment of brain injury, environmental health and performance, physiological and psychological health, injury prevention and reduction, medical simulation and training, health informatics, and rehabilitation.

| Exhibit R-2, RDT&E Budget Item Justification: PB 2014 Defense Health Program | DATE: March 2013 |
|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* |

For the Army Medical Command, the Hard Body Armor project focuses on scientific study and evaluation of injuries related to blunt trauma events on cadavers. Preventing blunt trauma injury is one of the critical components of body armor design.

For the Army Medical Command, the Underbody Blast Testing medical research project provides funds to establish a scientific and statistical basis for evaluating skeletal injuries to vehicle occupants during ground vehicle Underbody Blast (UBB) events. Areas of interest to the Secretary of Defense are medical research that provides an understanding of the human tolerance limits and injury mechanisms needed to accurately predict skeletal injuries to ground combat vehicle occupants caused by UBB events.

For the Navy Bureau of Medicine and Surgery, this program element includes funds for research management support costs. The Outside Continental US (OCONUS) laboratories conduct focused medical research on vaccine development for Malaria, Diarrhea Diseases, and Dengue Fever. In addition to entomology, HIV studies, surveillance and outbreak response under the Global Emerging Infections Surveillance (GEIS) program and risk assessment studies on a number of other infectious diseases that are present in the geographical regions where the laboratories are located. The CONUS laboratories conduct research on Military Operational Medicine, Combat Casualty Care, Diving and Submarine Medicine, Infectious Diseases, Environmental and Occupational Health, Directed Energy, and Aviation Medicine and Human Performance.

For the Army Medical Command, beginning in FY14, military human immunodeficiency virus (HIV) research program funding is transferred from the Army to the Defense Health Program. This project funds research to develop candidate HIV vaccines, to assess their safety and effectiveness in human subjects, and to protect the military personnel from risks associated with HIV infection. In addition, the research is designed to find ways to protect the blood supply from contamination with HIV virus.

For the Army Medical Command, the Armed Forces Pest Management Board (AFPMB) Deployed Warfighter Protection project provides for the development of new or improved protection of ground forces from disease carrying insects.

For the Army Medical Command, four Centers of Excellence (CoE) receive Medical Technology Development funds. The Breast Cancer Center of Excellence (Army) provides a multidisciplinary approach as the standard of care for treating breast diseases and breast cancer. The Gynecologic Center of Excellence (Army) focuses on characterizing the molecular alterations associated with benign and malignant gynecologic disease and facilitates the development of novel early detection, prevention and novel biologic therapeutics for the management of gynecologic disease. The Cardiac Health Center of Excellence (Army) provides evidence-based personalized patient engagement approaches for comprehensive cardiac event prevention through education, outcomes research and technology tools, as well as molecular research to detect cardiovascular (CV) disease at an early stage to ultimately discover a signature for CV health, to find new genes that significantly increase risk for heart attack in Service members and other beneficiaries, and identify molecular markers of obesity and weight loss. The Pain Center of Excellence (Army) examines the relationship between acute and chronic pain and focuses on finding, implementing, and evaluating the most effective methods of relieving the acute pain caused by combat trauma and the effect this has throughout the continuum to rehabilitation and reintegration.

| Exhibit R-2, RDT&E Budget Item Justification: PB 2014 Defense Health Program | DATE: March 2013 |
|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* |

For the Air Force Medical Service, funding in this program element supports the Air Force Surgeon General's vision for medical modernization through a robust research & development program. It funds advanced technology development within the following research thrust/project areas: Expeditionary Medicine, En-Route Care, Force Health Protection, Operational Medicine, and Human Performance, with the intent to support solutions that answer Air Force specific needs. During this process, the efforts of other government agencies in those areas will be assessed to avoid redundancy.

For the Uniformed Services University of the Health Sciences (USUHS), Medical Development programs include the Neuroscience CoE, the Prostate Cancer CoE, and the Center for Neuroscience and Regenerative Medicine. The Neuroscience Center of Excellence (CoE), formerly a Congressional Special Interest program, was chartered in 2002 to conduct basic, clinical and translational research studies of militarily relevant neurological disorders affecting US service members and military medical beneficiaries. The Center's mission is to improve prevention, diagnosis and treatment of neurological disorders that directly affect warfighters through a multi-site research program that collaborates broadly with military, civilian and federal medical institutions. The Prostate CoE, formerly a Congressional Special Interest program, was chartered in 1992 to conduct basic, clinical and translational research programs to combat diseases of the prostate. The program's mission is fulfilled primarily through its three principal programs- the Clinical Translational Research Center, the Basic Science Research Program and the Tri-Service Multicenter Prostate Cancer Database which encompasses its clinical research work with other participating military medical centers. These affiliated sites contribute data and biospecimens obtained from prostate cancer patients and participate in clinical trials. The Center for Neuroscience and Regenerative Medicine (CNRM) brings together the expertise of clinicians and scientists across disciplines to catalyze innovative approaches to traumatic brain injury (TBI) research. CNRM Research Programs emphasize aspects of high relevance to military populations, with a primary focus on patients at the Walter Reed National Military Medical Center.

In FY12, DHP funded the following Congressional Special Interest (CSI) peer-reviewed directed research: Amyotrophic Lateral Sclerosis (ALS); Autism; Bone Marrow Failure Disease; Ovarian Cancer; Multiple Sclerosis; Cancer; Lung Cancer; Orthopedic Research; Spinal Cord Research; Vision; Traumatic Brain Injury and Psychological Health; Breast Cancer; Prostate Cancer; Gulf War Illness; Alcohol and Substance Use Disorders; Medical Research; Alzheimer Research; Pain Management Task Force; Blast Recovery Monitors; Armed Forces Institute of Regenerative Medicine; Hemorrhage Control; Joint Warfighter Medical Research; Restorative Transplantation; Global HIV/AIDS Prevention; Tuberous Sclerosis Complex; and Duchenne Muscular Dystrophy. Because of the CSI annual structure, out-year funding is not programmed.

| Exhibit R-2, RDT&E Budget Item Justification: PB 2014 Defense Health Program | DATE: March 2013 |
|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* |

| B. Program Change Summary ($ in Millions) | FY 2012 | FY 2013 | FY 2014 Base | FY 2014 OCO | FY 2014 Total |
|---|---|---|---|---|---|
| Previous President's Budget | 703.313 | 239.110 | 283.741 | - | 283.741 |
| Current President's Budget | 713.880 | 239.110 | 290.852 | - | 290.852 |
| Total Adjustments | 10.567 | 0.000 | 7.111 | - | 7.111 |
| • Congressional General Reductions | - | - | | | |
| • Congressional Directed Reductions | - | - | | | |
| • Congressional Rescissions | - | - | | | |
| • Congressional Adds | - | - | | | |
| • Congressional Directed Transfers | - | - | | | |
| • Reprogrammings | - | - | | | |
| • SBIR/STTR Transfer | 10.567 | - | | | |
| • New Project - Military HIV Research Program | - | - | 7.111 | - | 7.111 |

| Congressional Add Details ($ in Millions, and Includes General Reductions) | FY 2012 | FY 2013 |
|---|---|---|
| **Project:** 300A: *CSI - Congressional Special Interests* | | |
| Congressional Add: *245A - Amyotrophic lateral Sclerosis (ALS) Research* | 6.400 | - |
| Congressional Add: *293A - Autism Research* | 5.100 | - |
| Congressional Add: *296A - Bone Marrow Failure Disease Research* | 3.200 | - |
| Congressional Add: *310A - Ovarian Cancer Research* | 16.000 | - |
| Congressional Add: *328A - Multiple Sclerosis Research* | 3.800 | - |
| Congressional Add: *335A - Peer-Reviewed Cancer Research* | 12.800 | - |
| Congressional Add: *336A - Peer-Reviewed Lung Cancer Research* | 10.200 | - |
| Congressional Add: *337A - Peer-Reviewed Orthopedic Research* | 30.000 | - |
| Congressional Add: *338A - Peer-Reviewed Spinal Cord Research* | 9.600 | - |
| Congressional Add: *339A - Peer-Reviewed Vision Research* | 3.200 | - |
| Congressional Add: *352A - Traumatic Brain Injury/ Psychological Health Research* | 86.000 | - |
| Congressional Add: *380A - Peer-Reviewed Breast Cancer Research* | 120.000 | - |
| Congressional Add: *390A - Peer-Reviewed Prostate Cancer Research* | 80.000 | - |
| Congressional Add: *392A - Gulf War Illness Peer-Reviewed Research* | 10.000 | - |
| Congressional Add: *396A - Research in Alcohol and Substance Use Disorders* | 4.500 | - |

| Exhibit R-2, RDT&E Budget Item Justification: PB 2014 Defense Health Program | DATE: March 2013 |
|---|---|
| **APPROPRIATION/BUDGET ACTIVITY**<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | **R-1 ITEM NOMENCLATURE**<br>PE 0603115HP: *Medical Technology Development* |

| Congressional Add Details ($ in Millions, and Includes General Reductions) | FY 2012 | FY 2013 |
|---|---|---|
| Congressional Add: *400A - Peer-Reviewed Medical Research* | 50.000 | - |
| Congressional Add: *417A - Peer-Reviewed Alzheimer Research* | 12.000 | - |
| Congressional Add: *438A - Peer-Reviewed Hemorrhage Control Research* | 6.000 | - |
| Congressional Add: *439A - Joint Warfighter Medical Research* | 40.000 | - |
| Congressional Add: *443A - Peer-Reviewed Restorative Transplantation Research* | 15.000 | - |
| Congressional Add: *540A - Global HIV/AIDS Prevention (Navy)* | 8.000 | - |
| Congressional Add: *660A - Tuberous Sclerosis Complex (TSC)* | 5.100 | - |
| Congressional Add: *790A - Duchenne Muscular Dystrophy* | 3.200 | - |
| Congressional Add Subtotals for Project: 300A | 540.100 | 0.000 |
| Congressional Add Totals for all Projects | 540.100 | 0.000 |

**Change Summary Explanation**

FY 2012: Restore FY 2013 President's Budget decrease to Congressional Special Interest from DHP RDT&E PE 0605502-Small Business Innovation Research (SBIR) Program (-$13.302 million) to DHP RDT&E, PE 0603115- Medical Technology Development (+$13.302 million).

Realign DHP RDT&E, PE 0603115-Medical Technology Development (-$2.735 million) to DHP RDT&E PE 0605502-Small Business Innovation Research (SBIR) Program (+$2.735 million).

FY 2013: No Change

FY 2014: Change Proposal increase to DHP RDT&E, PE 0603115-Medical Technology Development (+$7.111 million) for the Military HIV Research Program (MHRP) from RDT&E, Army, appropriation.

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | | DATE: March 2013 |
|---|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>300A: *CSI - Congressional Special Interests* | |

| COST ($ in Millions) | All Prior Years | FY 2012 | FY 2013# | FY 2014 Base | FY 2014 OCO ## | FY 2014 Total | FY 2015 | FY 2016 | FY 2017 | FY 2018 | Cost To Complete | Total Cost |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 300A: *CSI - Congressional Special Interests* | - | 540.100 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |

# FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

## The FY 2014 OCO Request will be submitted at a later date

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

In FY12, the Defense Health Program funded Congressional Special Interest (CSI) directed research. The strategy for the FY12 Congressionally directed research is to stimulate innovative research through a competitive, peer-reviewed research program, and focused medical research at intramural and extramural research sites. Specific peer-reviewed research efforts include the following: Amyotrophic Lateral Sclerosis (ALS); Autism; Bone Marrow Failure Disease; Ovarian Cancer; Multiple Sclerosis; Cancer; Lung Cancer; Orthopedic Research; Spinal Cord Research; Vision; Traumatic Brain Injury and Psychological Health; Breast Cancer; Prostate Cancer; Gulf War Illness; Alcohol and Substance Use Disorders; Medical Research; Alzheimer Research; Hemorrhage Control; Joint Warfighter Medical Research; Restorative Transplantation; Global HIV/AIDS Prevention; Tuberous Sclerosis Complex; and Duchenne Muscular Dystrophy. Because of the CSI annual structure, out-year funding is not programmed.

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2012 | FY 2013 |
|---|---|---|
| ***Congressional Add:*** 245A - Amyotrophic lateral Sclerosis (ALS) Research | 6.400 | - |
| ***FY 2012 Accomplishments:*** This Congressional Special Interest was directed toward research on Amyotrophic Lateral Sclerosis (ALS), also known as Lou Gehrig's disease. The ALS Research Program is a broadly competed, peer-reviewed research program. Its focus is to investigate new drugs to control and/or cure this disease. Two award mechanisms were offered in 2012, the Therapeutic Development Award and the Therapeutic Idea Award. Proposals were received in July 2012, followed by peer review in September 2012, and the funding/programmatic review in December 2012. Awards will be finalized no later than September 2013. | | |
| ***Congressional Add:*** 293A - Autism Research | 5.100 | - |
| ***FY 2012 Accomplishments:*** This Congressional Special Interest research initiative for Autism Research sought to improve treatment outcomes of Autism Spectrum Disorders (ASD), led to a better understanding of ASD; and integrated basic science and clinical observations by promoting innovative research. Two award mechanisms were offered in FY12: Idea Development Award and the Pilot Award. The Autism Research Program has funded research at universities, hospitals, nonprofit and for-profit institutions, as well as private industry. Proposals were received in September 2012, peer review was conducted in November 2012, and | | |

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | DATE: March 2013 |
|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>300A: *CSI - Congressional Special Interests* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2012 | FY 2013 |
|---|---|---|
| programmatic review for funding recommendations will be done in January 2013. Award(s) will be made by September 2013. | | |
| ***Congressional Add:*** 296A - Bone Marrow Failure Disease Research | 3.200 | - |
| ***FY 2012 Accomplishments:*** This Congressional Special Interest research initiative was for bone marrow failure diseases. The mission of the program was to sponsor innovative research that will advance the understanding of inherited and acquired bone marrow failure diseases; to improve the health and life of individuals living with these diseases, with the ultimate goal of prevention and/or cure. This effort has solicited research proposals focused on bone marrow failure syndromes and their long-term effects from the basic science and clinical research sectors. In Fiscal Year 2012, applications were accepted through two funding opportunities, the Idea Award and the Post-doctoral Fellowship Training Award. Application receipt was completed in July 2012, peer review was conducted in September 2012, and funding recommendations were made during programmatic review in November 2012. Nine awards were approved for funding and will be made by September 2013. | | |
| ***Congressional Add:*** 310A - Ovarian Cancer Research | 16.000 | - |
| ***FY 2012 Accomplishments:*** This Congressional Special Interest research initiative was for studying Ovarian Cancer. The overall goal of the program was to eliminate ovarian cancer by supporting high impact, innovative research. In striving to achieve this goal, the Fiscal Year 2012 Ovarian Cancer Research Program (OCRP) was supporting innovative ideas that will provide new paradigms, leveraging critical resources, facilitating synergistic, multidisciplinary partnerships, and cultivating the next generation of investigators in ovarian cancer. Five award mechanisms were offered: Ovarian Cancer Academy Award, Outcomes Consortium Development Award, Pilot Award, Synergistic Translational Leverage Award, and Teal Innovator Award. Applications were due in July/August 2012; scientific peer review took place in September 2012 with programmatic review being held in November 2012. 21 awards were recommended for funding and will be made by September 2013. | | |
| ***Congressional Add:*** 328A - Multiple Sclerosis Research | 3.800 | - |
| ***FY 2012 Accomplishments:*** This Congressional Special Interest research initiative was for Multiple Sclerosis (MS). The mission of the program was to support pioneering concepts and high impact research relevant to the etiology, pathogenesis, assessment and treatment of MS with the vision of preventing the occurrence, curing, reversing or slowing the progression, and lessening the personal and societal impact of MS. This effort solicited research proposals from the basic science and clinical research sectors. Applications were accepted through one funding opportunity; the Idea Development Award mechanism. Applications receipt was complete in July 2012; scientific peer review was conducted in September 2012; and funding recommendations were made | | |

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | DATE: March 2013 |
|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>300A: *CSI - Congressional Special Interests* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2012 | FY 2013 |
|---|---|---|
| during programmatic review in November 2012. Six awards were recommended for funding and will be made by September 2013. | | |
| ***Congressional Add:*** 335A - Peer-Reviewed Cancer Research<br><br>***FY 2012 Accomplishments:*** This Congressional Special Interest research initiative was for the study of cancers designated by Congress. The goal of the Peer Reviewed Cancer Research Program was to improve the quality of life by significantly decreasing the impact of cancer on service members, their families, and the American public. The funds appropriated by Congress are directed for research in the following areas: blood cancers, colorectal cancer, genetic cancer research, kidney cancer, Listeria vaccine for cancer, melanoma and other skin cancers, mesothelioma, pancreatic cancer, and pediatric brain tumors. Two award mechanisms to support these topic areas were released: the Career Development Award and the Visionary Postdoctoral Fellowship Award. Receipt was in September 2012, scientific peer review took place in November 2012 and funding recommendations will be made at the programmatic review in January 2013. Awards will be made by 30 September 2013. | 12.800 | - |
| ***Congressional Add:*** 336A - Peer-Reviewed Lung Cancer Research<br><br>***FY 2012 Accomplishments:*** This Congressional Special Interest research initiative was for studying Lung Cancer. It seeked to eradicate deaths from lung cancer to better the health and welfare of the military and the American public. As such, the Lung Cancer Research Program (LCRP) will support and integrate research from multiple disciplines for risk assessment, early detection, diagnosis, prevention, cure and control of lung cancer. Three award mechanisms were offered in 2012, the Idea Development Award, the Translation Research Partnership Award, and the Concept Award. Proposals were received in August/September 2012; scientific peer review was conducted in October/November 2012; and programmatic review for funding recommendations will be made in January 2013. Award(s) will be made by September 2013. | 10.200 | - |
| ***Congressional Add:*** 337A - Peer-Reviewed Orthopedic Research<br><br>***FY 2012 Accomplishments:*** This Congressional Special Interest research initiative was to support orthopaedic research that will advance optimal treatment and rehabilitation from musculoskeletal injuries sustained during combat or combat-related activities. The vision was to provide all warriors affected by orthopaedic injuries sustained in defense of our Constitution the opportunity for optimal recovery and restoration of function. The effort solicits innovative, high impact and clinically-relevant research, with a focus on collaborations between military and non-military researchers and clinicians. Three award mechanisms have been offered in Fiscal Year 2012: Clinical Trial, Translational Research Partnership, and Idea Development Awards. Pre-applications were due in June 2012 and applications were due in September 2012; scientific peer review took place in November | 30.000 | - |

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | DATE: March 2013 |
|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>300A: *CSI - Congressional Special Interests* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2012 | FY 2013 |
|---|---|---|
| 2012; and programmatic review for funding recommendations will be held in January 2013. Award(s) will be made by September 2013. | | |
| ***Congressional Add:*** 338A - Peer-Reviewed Spinal Cord Research | 9.600 | - |
| ***FY 2012 Accomplishments:*** This Congressional Special Interest research initiative was to support Spinal Cord Injury (SCI) research. Within this context, this initiative focuses its funding on innovative projects that have the potential to make a significant impact on the health and well-being of military service members, Veterans, and other individuals living with SCI. This research effort offered three award mechanisms in Fiscal Year 2012 to support SCI research: Clinical Trial, Investigator-Initiated Research, and Translational Research Awards. Pre-applications were due in July 2012 and applications were due in October 2012; scientific peer review took place in November 2012; and programmatic review for funding recommendations will be held in January 2013. Award(s) will be made by September 2013. | | |
| ***Congressional Add:*** 339A - Peer-Reviewed Vision Research | 3.200 | - |
| ***FY 2012 Accomplishments:*** This Congressional Special Interest research effort for Peer Reviewed Vision Research targeted the causes, effects and treatments of eye damage, visual deficits due to traumatic brain injury (TBI) and diseases that, despite their different pathogenesis (mechanisms that occur during disease development), all have a common end result: degeneration of the critical components of the eye and impairment or loss of vision. The results of this research are intended to be used for restoration and maintaining of visual function to ensure and sustain combat readiness. Basic, translational and clinical research efforts are sought to ensure that results of scientific research will be used to directly benefit the lives of military, veteran and civilian populations. Critical areas to be researched include: inadequate vision rehabilitation strategies and quality of life measures; inadequate vision restoration; inadequate mitigation and treatment of traumatic injuries, war-related injuries, and diseases to ocular structures and the visual system; inadequate mitigation and treatment of visual dysfunction associated with traumatic brain injury (TBI); inadequate ocular and visual systems diagnostic capabilities and assessment strategies; and inadequate war fighter vision readiness and enhancement related to refractive surgery. To meet the goals of the program, two award mechanisms were developed to support vision research. These included the Investigator Initiated Research Award and the Hypothesis Development Award. The Investigator Initiated Research Awards had a total cost not to exceed $1.0M and a period of performance up to four years. The Hypothesis Development Awards had a total not to exceed $250K and a period of performance up to two years. One hundred and fifty one pre-proposals were received in September 2011 and 45 full proposals underwent scientific peer review in January 2012. A total of 22 proposals were recommended for funding in March 2012. | | |
| ***Congressional Add:*** 352A - Traumatic Brain Injury/ Psychological Health Research | 86.000 | - |

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | DATE: March 2013 |
|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>300A: *CSI - Congressional Special Interests* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2012 | FY 2013 |
|---|---|---|
| ***FY 2012 Accomplishments:*** The Traumatic Brain Injury and Psychological Health (TBI/PH) Congressional Special Interest project funding was divided into applied research, technology development and concept development efforts. The project aims to prevent, mitigate, and treat the effects of combat-relevant traumatic stress and TBI on function, wellness, and overall quality of life, including interventions across the deployment lifecycle for warriors, Veterans, family members, caregivers, and communities. A key priority of the TBI/PH Research Program is to complement ongoing DoD efforts to ensure the health and readiness of our military forces by promoting a better standard of care for PTSD and TBI in the areas of prevention, detection, diagnosis, treatment, and rehabilitation. Program Announcements, programmatic reviews, Service requested nominations, and ongoing studies that would benefit from program acceleration have been incorporated to address these priorities and gather proposals. In the area of TBI, researchers performed clinical trials to treat mild TBI with an oral drug, a trial using diffusion tensor imaging to diagnose mild TBI in service members, and a trial performed in partnership with the NIH looking for better ways to image TBI. Program announcements were released for proposals looking for advanced neurotrauma imaging techniques and for a new VA/DoD Trauma consortium which will be a five-year, multi-university consortium to discover mechanisms of treatment and the long-term effects of TBI and its relationship to Chronic Traumatic Encephalopathy (CTE). The VA will essentially match the funding supplied by DoD in this consortium. | | |
| ***Congressional Add:*** 380A - Peer-Reviewed Breast Cancer Research | 120.000 | - |
| ***FY 2012 Accomplishments:*** This Congressional Special Interest research initiative was to study Breast Cancer. The vision for this effort was to end breast cancer. Through a partnership between scientists and consumers, the Breast Cancer Research Program (BCRP) strives to fill important gaps in breast cancer research by funding innovative and potentially high-impact research ideas, by providing opportunities to pursue new research ideas that are early in development, by promoting collaborations and partnerships, and by supporting future innovators and leaders in the breast cancer field. To support this vision for Fiscal Year 2012, eight award mechanisms were developed to support meritorious breast cancer research: Clinical Translational Research Award, Collaborative Scholars and Innovators Award, Era of Hope Scholar Award, Idea Award, Impact Award, Innovator Award, Postdoctoral Fellowship Award, and Transformative Vision Award. Proposal receipt was completed in August 2012. Peer review was completed in October 2012, and funding recommendations will be made at programmatic reviews in August, November, and December 2012 and in January 2013. Award(s) will be made by September 2013. | | |
| ***Congressional Add:*** 390A - Peer-Reviewed Prostate Cancer Research | 80.000 | - |
| ***FY 2012 Accomplishments:*** This Congressional Special Interest research was for Prostate Cancer. The vision for this effort was to conquer prostate cancer by funding research to end suffering and death from | | |

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | DATE: March 2013 |
|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>300A: *CSI - Congressional Special Interests* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2012 | FY 2013 |
|---|---|---|
| prostate cancer. To address the most critical current needs in prostate cancer research and clinical care, the Prostate Cancer Research Program (PCRP) developed two overarching challenges to be addressed by the research community: (1) develop effective treatments for advanced disease, and (2) distinguish aggressive from indolent disease. In addition, research projects are solicited in the areas of biomarker development, genetics, imaging, mechanisms of resistance, survivorship and palliative care, therapy, and tumor and microenvironment biology. To meet these goals for Fiscal Year 2012, eleven award mechanisms were developed to support significant prostate cancer research. These included: Biomarker Development Award, Clinical Exploration Award, Collaborative Undergraduate HBCU Student Summer Training Program Award, Exploration-Hypothesis Development Award, Health Disparity Research Award, Idea Development Award, Laboratory-Clinical Transition Award, Physician Research Training Award, Postdoctoral Training Award, Synergistic Idea Development Award, and Transformative Impact Award. Application submission deadline occurred in June-August 2012; peer review took place in August and October 2012; and programmatic review for funding recommendations will be held in December 2012. Award(s) will be made by September 2013. | | |
| ***Congressional Add:*** 392A - Gulf War Illness Peer-Reviewed Research | 10.000 | - |
| ***FY 2012 Accomplishments:*** This Congressional Special Interest research initiative was for Gulf War Illness Research. The program's vision of improving the health and lives of veterans who have the complex symptoms known as Gulf War Illness is being addressed through the funding of innovative research to identify effective treatments, to improve its definition and diagnosis, and to better understand its pathobiology and symptoms. Applications were accepted for Fiscal Year 2012 through four award mechanisms: the Consortium Award, Clinical Trial Award, Innovative Treatment Evaluation Award, and Investigator-Initiated Research Award. Program announcements were released in March 2012, scientific peer review took place in July and September 2012, and funding recommendations will be made at programmatic review in September and December 2012. Awards will be made by September 2013. | | |
| ***Congressional Add:*** 396A - Research in Alcohol and Substance Use Disorders | 4.500 | - |
| ***FY 2012 Accomplishments:*** This Congressional Special Interest research effort on Research in Alcohol and Substance Use Disorders has established a competitive program to create translational research addressing alcohol and substance abuse issues. The goal of this project was to develop new treatments for those struggling with alcohol and substance abuse who also suffer from post-traumatic stress disorder and/or traumatic brain injury. This comes at a crucial time as alcohol and substance abuse continues to rise among service members. The Programs are comprised of collaborative, multidisciplinary teams of leading scientists and individual investigators from a group of world-class research institutions. The objective is to ultimately bring together multidisciplinary teams and investigators, including basic, translational, and clinical scientists, into cooperative | | |

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | DATE: March 2013 |
|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>300A: *CSI - Congressional Special Interests* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2012 | FY 2013 |
|---|---|---|
| and synergistic working groups. In this fiscal year the program released its initial call for proposals. Submitted proposals came from a representation of the leading alcohol research institutional partners from around the country and underwent a rigorous scientific peer review. Based on the review in July of 2012 the top 10 proposal were awarded. The 10 awarded projects span from basic science work exploring novel targets and pharmacological (drug) treatment to medication trials. Additionally in this fiscal year the program developed and began implementation of a translational coordinating core. The core's purpose is to guide, direct, and accelerate the exploitation of the discoveries of the research consortium and funded awards in identifying the most promising pharmacological targets, validating their usefulness for substance disorder treatment in the context of common mental health challenges found in service members and veterans. | | |
| ***Congressional Add:*** 400A - Peer-Reviewed Medical Research | 50.000 | - |
| ***FY 2012 Accomplishments:*** This Congressional Special Interest research addressed peer reviewed medical research. The vision of the program is to identify and fund the best medical research to protect and support warfighters, veterans, and other beneficiaries and to eradicate diseases that impact these populations. Research proposals submitted to the Fiscal Year 2012 (FY12) program must focus on at least one of the 22 Congressionally-directed topics. These topic areas are: arthritis; composite tissue transplantation; drug abuse; dystonia; epilepsy; food allergies; fragile X syndrome; hereditary angioedema; inflammatory bowel disease; interstitial cystitis; Listeria vaccine for infectious disease; lupus; malaria; nanomedicine for drug delivery science; neuroblastoma; osteoporosis and related bone disease; Paget's disease; polycystic kidney disease; post-traumatic osteoarthritis; scleroderma; tinnitus; and tuberculosis. In FY12, applications were accepted through four funding opportunities: the Investigator-Initiated Research Award, Technology/Therapeutic Development Award, Concept Award, and Clinical Trial Award mechanisms. Application receipt was completed in May and June 2012; scientific peer review was conducted in July-September 2012; and funding recommendations will be made during programmatic review in December 2012. Award(s) will be made by September 2013. | | |
| ***Congressional Add:*** 417A - Peer-Reviewed Alzheimer Research | 12.000 | - |
| ***FY 2012 Accomplishments:*** The goal of the Militarily Relevant Peer Reviewed Alzheimer's (MRPRA) Congressional Special Interest Research Program was to gain an understanding of the genesis of Traumatic Brain Injury (TBI)-associated neurodegenerative disease. Equally important, the MRPRA Research Program also sought to invest in new strategies dedicated to improving the quality of life for those affected by Alzheimer's disease. The MRPRA employs a 2-tiered review of scientific and programmatic review. The programmatic review was completed by the MRPRA's Program Steering Committee, comprised of governmental, military, and not for profit experts. To date, the MRPRA has received FY11 and FY12 funding ($15M and $12M, respectively). Fifteen projects were funded with FY11 dollars, including the Vietnam Veterans Alzheimer's | | |

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | DATE: March 2013 |
|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>300A: *CSI - Congressional Special Interests* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2012 | FY 2013 |
|---|---|---|
| Disease Neuroimaging Initiative study. Funding recommendations for the FY12 program will be finalized by Spring of 2013. Two FY12 award mechanisms were available on Grants.gov; one of which is intended to support studies with military cohorts. The mechanisms are the Convergence Science Research Award, and the Military Risk Factors Research Award. The MRPRA anticipates funding roughly 10 projects with FY12 funds. | | |
| ***Congressional Add:*** 438A - Peer-Reviewed Hemorrhage Control Research<br><br>***FY 2012 Accomplishments:*** The Congressional Special Interest for Peer-Reviewed Hemorrhage Control Research was intended to seek solutions to uncontrolled bleeding without clotting resulting from severe trauma. A major international trial found that use of Tranexamic Acid (TXA) for hemorrhage (bleeding) reduced trauma deaths by 15% but subsequent analysis showed increased deaths in certain populations. Research and clinical studies are being initiated to clarify the exclusion criteria for using this drug in combat wounded patients. | 6.000 | - |
| ***Congressional Add:*** 439A - Joint Warfighter Medical Research<br><br>***FY 2012 Accomplishments:*** The Joint Warfighter Medical Research Program Congressional Special Interest was intended to provide continuing support for promising previously CSI-funded projects, and to augment and accelerate high priority DoD and Service medical requirements that are close to achieving their objectives and yielding a benefit to military medicine. Project funding is divided into technology development and concept development efforts. The technology development efforts support military medical research in combat casualty care, military operational medicine, medical training and health information sciences, and clinical rehabilitative medicine to include pain management, regenerative medicine, and sensory system (hearing and sight) rehabilitation and restoration. Through an iterative process of recommendations, several prior years of CSI-funded projects nominated by the Services, CSI managers, and execution activities were invited to submit augmented preproposals through the US Army Medical Research and Materiel Command Broad Agency Announcement. Based on these preproposals a programmatic review committee prioritized the research initiatives and the prioritization was approved by DoD Health Affairs in early September. Full proposals were received through the Broad Agency Announcement in late September and peer reviewed by the contracting officer representative and then evaluated through a second tier review and approved for funding in early November in accordance with the prioritization plan. Contract awards will be completed during the latter part of the first quarter and the second quarter of FY 13. | 40.000 | - |
| ***Congressional Add:*** 443A - Peer-Reviewed Restorative Transplantation Research<br><br>***FY 2012 Accomplishments:*** This Congressional Special Interest research initiative for Restorative Transplantation Research was to fund research to accelerate and improve methods related to hand and face transplants through multi-institutional and multi-disciplinary partnership award(s). The Program Announcement | 15.000 | - |

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | DATE: March 2013 |
|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>300A: *CSI - Congressional Special Interests* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2012 | FY 2013 |
|---|---|---|
| focus areas are: (1) Applied research to prevent immune rejection, (2) Clinical monitoring of transplant recipients, and (3) Standardization of processes and protocols. In FY 2012, a program announcement was developed. The announcement was released in October 2012 and closes in December 2012. Scientific peer review is scheduled to occur in February 2013. Funding recommendations will be made at programmatic review in 2013 and awards will be made by 30 September 2013. | | |
| ***Congressional Add:*** 540A - Global HIV/AIDS Prevention (Navy)<br><br>***FY 2012 Accomplishments:*** Program emphasis is placed on (1) building a national research infrastructure by funding large, multidisciplinary program projects focused on detection; (2) encouraging innovative approaches to research by funding new ideas and technology with or without supporting preliminary data; and (3) recruiting new, independent investigators for careers in research, as well as more senior investigators new to the research field. The strategy for the FY 2011 Congressionally directed research identified above is to stimulate innovative research through a competitive, peer reviewed research program, as well as focused medical research at intramural and extramural research sites. Specific research efforts include HIV/AIDS. The HIV/AIDS Prevention program conducts on-site visits to determine eligible areas for technical assistance and resource support. HIV/AIDS provides support to defense forces in the following areas: (1) HIV prevention, which includes training of medical personnel and peer educators, education of military members, provision of condoms and other prevention materials, provision of educational materials such as brochures, posters, and booklets (2) care for HIV-infected individuals and their families to include provision of electronic medical record programs, medications to treat HIV-related issues, physician education, and clinic infrastructure support, (3) treatment services including provision of laboratory services such as HIV test kits, and other laboratory equipment, and (4) Strategic Information including systems to collect information on the effectiveness of HIV treatment and prevention programs and generate databases of such information to guide treatment and prevention programs. The HIV/AIDS Prevention Program provided technical assistance and resource support for 35 foreign defense forces in FY 2011. Accomplishments include over 49,500 individuals that received testing and counseling services for HIV and received their test results, 97,800 military members and their dependents targeted with HIV prevention interventions, more than 950 health care workers successfully completing an in-service training program, and 4,053 pregnant women knew their HIV status based on testing and counseling services provided to them. Accomplishments for FY 2012 will be reported after the end of the 2012 fiscal year once annual program result data is collected. Because of the CSI annual structure, out-year funding is not programmed. | 8.000 | - |
| ***Congressional Add:*** 660A - Tuberous Sclerosis Complex (TSC)<br><br>***FY 2012 Accomplishments:*** The Congressional Special Interest research initiative for Tuberous Sclerosis Complex (TSC) focused on promoting innovative research focused on decreasing the clinical impact of TSC. | 5.100 | - |

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | DATE: March 2013 |
|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>300A: *CSI - Congressional Special Interests* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2012 | FY 2013 |
|---|---|---|
| Within this context, this initiative encouraged applications that address a number of vital focus areas. This research effort offered three award mechanisms to support TSC research: Idea Development, Exploration-Hypothesis Development, and Clinical Trial Awards. Proposals were received in May 2012, peer review was conducted in July 2012, and funding recommendations were made at programmatic review in September 2012. Nine awards were recommended for funding and will be made by September 2013. | | |
| ***Congressional Add:*** 790A - Duchenne Muscular Dystrophy<br><br>***FY 2012 Accomplishments:*** This Congressional Special Interest research initiative was for research focused on Duchenne Muscular Dystrophy (DMD). The vision for this effort is to extend and improve the function, quality of life, and lifespan for all individuals diagnosed with DMD by supporting research to accelerate the development and clinical testing of new therapeutics and increase the understanding of successes and failures of clinical trials. Two award mechanisms were offered in 2012, the Investigator-Initiated Research Award and the Therapeutic Idea Award. Applications were due in November 2012; scientific peer review will take place in January 2013; and programmatic review will be held in February 2013. Award(s) will be made by September 2013. | 3.200 | - |
| **Congressional Adds Subtotals** | 540.100 | 0.000 |

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

N/A

**Remarks**

**D. Acquisition Strategy**

Work under this PE will be solicited by traditional Program Announcements resulting in contracts or other transactions.

**E. Performance Metrics**

N/A

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | | DATE: March 2013 |
|---|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>238C: *Enroute Care Research & Development (Budgeted) (AF)* | |

| COST ($ in Millions) | All Prior Years | FY 2012 | FY 2013# | FY 2014 Base | FY 2014 OCO ## | FY 2014 Total | FY 2015 | FY 2016 | FY 2017 | FY 2018 | Cost To Complete | Total Cost |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 238C: *Enroute Care Research & Development (Budgeted) (AF)* | - | 3.261 | 6.000 | 4.800 | - | 4.800 | 4.500 | 4.200 | 4.400 | 4.479 | Continuing | Continuing |

# FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

## The FY 2014 OCO Request will be submitted at a later date

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

Enroute Care Research & Development (Air Force): This project area seeks to advance aeromedical transport capabilities through the research and development of rapid, more efficient, and safer patient transport from the point of injury to definitive care and to understand the effects of altitude on seriously injured war fighters. Efforts will focus on translating technological advancements and groundbreaking clinical research into transitionable products. The sub-project areas include: Physiological Effects of Aeromedical Evacuation on patients and crew, impact of transport times on En-Route Trauma and Resuscitative Care, and En-Route Patient Safety. Because patients experience multiple handoffs between teams of caregivers during transport between austere environments and definitive care, efforts in this sub-project area examine human factors considerations in en-route patient safety in order to develop new and enhance existing methods to mitigate risk in all en-route care environments.

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2012 | FY 2013 | FY 2014 |
|---|---|---|---|
| ***Title:*** Enroute Care Research & Development (Budgeted) (AF) | 3.261 | 6.000 | 4.800 |

***Description:*** Enroute Care Research & Development (Air Force): This project area seeks to advance aeromedical transport capabilities through the research and development of rapid, more efficient, and safer patient transport from the point of injury to definitive care and to understand the effects of altitude on seriously injured war fighters. Efforts will focus on translating technological advancements and groundbreaking clinical research into transitionable products. The sub-project areas include: Physiological Effects of Aeromedical Evacuation on patients and crew, impact of transport times on En-Route Trauma and Resuscitative Care, and En-Route Patient Safety. Because patients experience multiple handoffs between teams of caregivers during transport between austere environments and definitive care, efforts in this sub-project area examine human factors considerations in en-route patient safety in order to develop new and enhance existing methods to mitigate risk in all en-route care environments.

***FY 2012 Accomplishments:***

Transitioned simulator mannequins to Center for Sustainment of Trauma and Readiness Skills/CSTARS-Cincinnati, USAF School of Aerospace Medicine and Critical Care Air Transport Team (CCATT) Pilot Units for use in ground training of AE and CCATT staff, and continued testing for Air Worthiness certification. Worked with Air Mobility Command and the joint Enroute Care community to finalize materiel and research priorities. Initiated research to enhance the care of acutely injured AE trauma patients through the assessment of closed loop technology for autonomous control of oxygenation and ventilation, and the evaluation of

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | DATE: March 2013 |
|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>238C: *Enroute Care Research & Development (Budgeted) (AF)* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2012 | FY 2013 | FY 2014 |
|---|---|---|---|
| a miniaturized extracorporeal membrane oxygenation system/ECMO device which serves as an external lung. Initiated research assessing the clinical effect of prolonged hypobaria during AE, how AE affects blood volume responsiveness, pain assessment during AE, and factors impacting patient safety during AE.<br>***FY 2013 Plans:***<br>Complete Air Worthiness certification for simulator mannequin and initiate use on AE and CCATT training flights. Continue research to enhance the care of acutely injured AE trauma patients though projects assessing closed loop technology for autonomous control of oxygenation and ventilation and evaluating a miniaturized extracorporeal membrane oxygenation system/ ECMO device which serves as an external lung. Initiate Air Worthiness certification on the miniaturized ECMO device and investigate FDA requirements. Analyze initial results of research assessing the clinical effect of prolonged hypobaria during AE, how AE affects blood volume responsiveness, pain assessment during AE, and factors impacting patient safety during AE. Assess how the transport of psychiatric patients impacts AE crew protocols. Perform a retrospective study on the effectiveness of AE life saving interventions during OIF/OEF. Investigate advanced development options for AE material solutions such as a portable power source, and in conjunction with the Expeditionary Medicine Thrust Area, a multi-channel negative pressure wound therapy device.<br>***FY 2014 Plans:***<br>Finalize FDA requirements and plan for transition of the miniaturized ECMO device to AMC for AE and CCATT use. Make recommendations regarding way-ahead on closed loop ventilation and oxygenation. Complete research assessing the clinical effect of prolonged hypobaria during AE, how AE affects blood volume responsiveness, pain assessment during AE, and factors impacting patient safety during AE. Apply the results of the effectiveness of life saving interventions study to modifying clinical practice guidelines. Identify FDA requirement and transition dates for AE material solutions. | | | |
| **Accomplishments/Planned Programs Subtotals** | 3.261 | 6.000 | 4.800 |

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

| Line Item | FY 2012 | FY 2013 | FY 2014 Base | FY 2014 OCO | FY 2014 Total | FY 2015 | FY 2016 | FY 2017 | FY 2018 | Cost To Complete | Total Cost |
|---|---|---|---|---|---|---|---|---|---|---|---|
| • BA-1, PE 0807714HP: *Other Consolidated Health Support* | 12.300 | 12.669 | 13.049 | | 13.049 | 13.441 | 13.844 | 14.259 | 14.655 | Continuing | Continuing |

**Remarks**

**D. Acquisition Strategy**

Broad Area Announcement (BAA) and Intramural calls for proposal are used to award initiatives in this program and project following determinatinons of scientific and technical merit, validation of need, prioritization, selection and any necessary legal and/or regulatory approvals (IRB, etc)

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | DATE: March 2013 |
|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>238C: *Enroute Care Research & Development (Budgeted) (AF)* |

**E. Performance Metrics**

Individual initiatives are measured through a quarterly annual project performance reporting system and program management review process -- performance is measured against standardized criteria for cost, schedule and performance (technical objectives) and key performance parameters. Variances, deviations and/or breaches in key areas are reviewed and a decision is rendered on any adjustments through a formalized process of S&T governance.

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | | DATE: March 2013 |
|---|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>243A: *Medical Development (Lab Support) (Navy)* | |

| COST ($ in Millions) | All Prior Years | FY 2012 | FY 2013# | FY 2014 Base | FY 2014 OCO ## | FY 2014 Total | FY 2015 | FY 2016 | FY 2017 | FY 2018 | Cost To Complete | Total Cost |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 243A: *Medical Development (Lab Support) (Navy)* | - | 33.555 | 35.453 | 37.434 | - | 37.434 | 38.198 | 39.558 | 40.222 | 40.942 | Continuing | Continuing |

# FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

## The FY 2014 OCO Request will be submitted at a later date

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

For the Navy Bureau of Medicine and Surgery, this program element (PE) includes RDT&E,HP funds for costs related to laboratory management and support salaries of government employees that are not paid from science/research competitively awarded funding. The Outside Continental U.S. (OCONUS) laboratories conduct focused medical research on vaccine development for Malaria, Diarrhea Diseases, and Dengue Fever. In addition to entomology, HIV studies, surveillance and outbreak response under the Global Emerging Infections Surveillance (GEIS) program and risk assessment studies on a number of other infectious diseases that are present in the geographical regions where the laboratories are located. The CONUS laboratories conduct research on Military Operational Medicine, Combat Casualty Care, Diving and Submarine Medicine, Infectious Diseases, Environmental and Occupational Health, Directed Energy, and Aviation Medicine and Human Performance.

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2012 | FY 2013 | FY 2014 |
|---|---|---|---|
| ***Title:*** Medical Development (Lab Support) (Navy) | 33.555 | 35.453 | 37.434 |
| ***Description:*** RDT&E funds for operating and miscellaneous support costs at RDT&E laboratories, including facility and civilian personnel costs that are not directly chargeable to RDT&E projects. Excludes military manpower and related costs, non-RDT&E base operating costs, and military construction costs which are included in other appropriate programs. | | | |
| ***FY 2012 Accomplishments:***<br>Provided operating and miscellaneous support costs at the Navy Bureau of Medicine and Surgery research laboratories. Provided support for technologically advanced cutting edge research equipment for research and data acquisition, automated sampling and real time statistical analysis of biomedical research data utilizing data information systems integral with new equipment. Replaced obsolescent general purpose research equipment. | | | |
| ***FY 2013 Plans:***<br>Continue to provide operating and miscellaneous support costs at BUMED research laboratories. Continue to provide support for technologically advanced cutting edge research equipment for research and data acquisition, automated sampling and real time statistical analysis of biomedical research data utilizing data information systems integral with new equipment. Continue to provide replacement of obsolescent general purpose research equipment. | | | |
| ***FY 2014 Plans:*** | | | |

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | DATE: March 2013 |
|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>243A: *Medical Development (Lab Support) (Navy)* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2012 | FY 2013 | FY 2014 |
|---|---|---|---|
| Continue to provide operating and miscellaneous support costs at BUMED research laboratories. Continue to provide support for technologically advanced cutting edge research equipment for research and data acquisition, automated sampling and real time statistical analysis of biomedical research data utilizing data information systems integral with new equipment. Continue to provide replacement of obsolescent general purpose research equipment.<br><br>Additional Funding received will be used will be use for 64 administrative civilian FTE's that had to be reprogrammed from the overhead account, due to new financial model. Funding will also be used for existing government inherent civilian vacancies that are not in the current manpower controls. | | | |
| **Accomplishments/Planned Programs Subtotals** | 33.555 | 35.453 | 37.434 |

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

N/A

**Remarks**

**D. Acquisition Strategy**

N/A

**E. Performance Metrics**

N/A

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | | DATE: March 2013 |
|---|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>284B: *USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (Budgeted) (AF)* | |

| COST ($ in Millions) | All Prior Years | FY 2012 | FY 2013# | FY 2014 Base | FY 2014 OCO ## | FY 2014 Total | FY 2015 | FY 2016 | FY 2017 | FY 2018 | Cost To Complete | Total Cost |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 284B: *USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (Budgeted) (AF)* | - | 2.421 | 4.400 | 3.800 | - | 3.800 | 3.800 | 5.700 | 5.871 | 5.977 | Continuing | Continuing |

# FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

## The FY 2014 OCO Request will be submitted at a later date

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

Human Performance (Human Physiology, Evaluation & Optimization) Research & Development (Air Force): This project area seeks to enhance, optimize & sustain performance of Air Force personnel through the evaluation and alleviation of health effects associated with carrying out assigned missions. This work addresses unique Air Force operational environments such as the mitigation of stress on personnel involved in remote piloted aircraft operations. The sub-project areas include: Cognitive Performance which includes fatigue management, Physiological Performance and Targeted Conditioning which includes training techniques for optimal performance, and identification of solutions related to Operational and Environmental Challenges to Performance.

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2012 | FY 2013 | FY 2014 |
|---|---|---|---|
| ***Title:*** USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (Budgeted) (AF) | 2.421 | 4.400 | 3.800 |
| ***Description:*** Human Performance (Human Physiology, Evaluation & Optimization) Research & Development (Air Force): This project area seeks to enhance, optimize & sustain performance of Air Force personnel through the evaluation and alleviation of health effects associated with carrying out assigned missions. This work addresses unique Air Force operational environments such as the mitigation of stress on personnel involved in remote piloted aircraft operations. The sub-project areas include: Cognitive Performance which includes fatigue management, Physiological Performance and Targeted Conditioning which includes training techniques for optimal performance, and identification of solutions related to Operational and Environmental Challenges to Performance. | | | |
| ***FY 2012 Accomplishments:***<br>Completed a comparison of the 1.5 mile run times study; resulted in a change in Air Force policy to increase the run time for Airman stationed at six high altitude bases, as of Jan 2012. Completed imaging studies on 85% of high altitude/U-2 pilots, and initiated baseline studies to establish comparison data. Completed Operationally Based Vision Assessment (OBVA) system testing at Wright Patterson AFB after system move from Mesa, AZ as part of the BRAC. | | | |
| ***FY 2013 Plans:*** | | | |

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | DATE: March 2013 |
|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>284B: *USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (Budgeted) (AF)* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2012 | FY 2013 | FY 2014 |
|---|---|---|---|
| Transition Operationally Based Vision Assessment (OBVA) into sustainment. Continue high altitude/U-2 pilot imaging and comparison baseline studies. Assess fatigue management using non-visual light stimulation, and the effects of Modafinil when used in combination with over-the-counter medications. Monitor ability to reduce injury through changes in training and sustainment physical training programs for Battlefield Airman.<br>***FY 2014 Plans:***<br>Complete high altitude/U-2 pilot imaging and comparison baseline studies. Address the use of synthetic tissue models as a viable training alternative to live animal use. Complete high altitude acclimation research. Pursue human systems integration studies. | | | |
| **Accomplishments/Planned Programs Subtotals** | 2.421 | 4.400 | 3.800 |

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

N/A

**Remarks**

SEE OTHER PROGRAM FUNDING SUMMARY FOR PROJECT CODE 238C WHICH IS A SUMMARY OF OTHER PROGRAM FUNDING SUPPORT TO ALL PROJECTS AND PROGRAMS IN THIS PE FOR DHP-AF

**D. Acquisition Strategy**

Broad Area Announcement (BAA) and Intramural calls for proposal are used to award initiatives in this program and project following determinatinons of scientific and technical merit, validation of need, prioritization, selection and any necessary legal and/or regulatory approvals (IRB, etc)

**E. Performance Metrics**

Individual initiatives are measured through a quarterly annual project performance reporting system and program management review process -- performance is measured against standardized criteria for cost, schedule and performance (technical objectives) and key performance parameters. Variances, deviations and/or breaches in key areas are reviewed and a decision is rendered on any adjustments through a formalized process of S&T governance.

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | | DATE: March 2013 |
|---|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>285A: *Operational Medicine Research & Development (Budgeted) (AF)* | |

| COST ($ in Millions) | All Prior Years | FY 2012 | FY 2013# | FY 2014 Base | FY 2014 OCO ## | FY 2014 Total | FY 2015 | FY 2016 | FY 2017 | FY 2018 | Cost To Complete | Total Cost |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 285A: *Operational Medicine Research & Development (Budgeted) (AF)* | - | 8.005 | 5.267 | 5.049 | - | 5.049 | 3.965 | 3.376 | 3.277 | 3.336 | Continuing | Continuing |

# FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

## The FY 2014 OCO Request will be submitted at a later date

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

This project area seeks to delineate more definitive patient care and treatment pertaining to Active Duty and beneficiary personnel in non-deployed settings. The sub-project areas include Clinical Patient Safety and Psychological Health and Resilience. The Psychological Health and Resilience sub-project area seeks to identify the sources of stress existing in a high operations tempo in-garrison healthcare staff in order to develop and transition countermeasures that provide or enable resilience. Other areas of interest include: translational research supporting the enhancement of patient education programs promoting healthy lifestyles that could impact the onset/prevention of conditions such as obesity and chronic diseases states and research to identify and validate risk variants impacting diseases such as autism.

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2012 | FY 2013 | FY 2014 |
|---|---|---|---|
| ***Title:*** Operational Medicine Research & Development (Air Force) | 8.005 | 5.267 | 5.049 |

***Description:*** This project area seeks to delineate more definitive patient care and treatment pertaining to Active Duty and beneficiary personnel in non-deployed settings. The sub-project areas include Clinical Patient Safety and Psychological Health and Resilience. The Psychological Health and Resilience sub-project area seeks to identify the sources of stress existing in a high operations tempo in-garrison healthcare staff in order to develop and transition countermeasures that provide or enable resilience. Other areas of interest include: translational research supporting the enhancement of patient education programs promoting healthy lifestyles that could impact the onset/prevention of conditions such as obesity and chronic diseases states and research to identify and validate risk variants impacting diseases such as autism.

***FY 2012 Accomplishments:***

Continued development of a aortic thoracic balloon occlusion device; finished initial model studies, completed prototype development, and scheduled testing of the prototype. Pursued research on the pathophysiology of corneal scar injury and the ability of photorefractive keratotomy to minimize corneal haze. Implemented Group Lifestyle Balance programs at six Air Force Medical Treatment Facilities (MTFs) using FY09 Congressional dollars. Initiated eight projects aimed at diabetes prevention using FY09 Congressional dollars. Completed FY09 Congressionally funded project on autism; research resulted in the identification of two genes associated with autism, the establishment of autism clinical services at Wright Patterson Air Force Base Medical Center, and enabled the participation of affected families at Wright Patterson in the Central Ohio Registry for Autism. Initiated a Congressionally funded project to test the integration of a FDA cleared diabetes management system using a mobile phone

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | DATE: March 2013 |
|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>285A: *Operational Medicine Research & Development (Budgeted) (AF)* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2012 | FY 2013 | FY 2014 |
|---|---|---|---|
| application into an electronic health record to assess the impact of real-time decision making on patient outcomes. Initiated follow-on research on autism to advance the work of the FY09 Congressional project. Initiated prevention and treatment research on obesity and asthma as pilot studies to establish a baseline for Patient-Centered Precision Care.<br>***FY 2013 Plans:***<br>Complete testing on thoracic aortic balloon occlusion prototype and finalize transition plans. Complete efforts on pathophysiology of corneal scar injury and the ability of photorefractive keratotomy to minimize corneal haze and investigate how results can be applied to revisions to clinical practice guidelines. Complete eight projects aimed at diabetes prevention using FY09 Congressional dollars. Continue university based diabetes research funded by Congressional dollars. Pursue research related to psychological health focusing on return to duty and resilience. Evaluate prevention and treatment outcomes related to Patient-Centered Precision Care.<br>***FY 2014 Plans:***<br>Building on previous work, concentrate on the evaluation of prevention and treatment of psychological health conditions and chronic disease initiatives related to Patient-Centered Precision Care. | | | |
| **Accomplishments/Planned Programs Subtotals** | 8.005 | 5.267 | 5.049 |

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

N/A

**Remarks**

**D. Acquisition Strategy**

Broad Area Announcement (BAA) and Intramural calls for proposal are used to award initiatives in this program and project following determinations of scientific and technical merit, validation of need, prioritization, selection and any necessary legal and/or regulatory approvals (IRB, etc)

**E. Performance Metrics**

Individual initiatives are measured through a quarterly annual project performance reporting system and program management review process -- performance is measured against standardized criteria for cost, schedule and performance (technical objectives) and key performance parameters. Variances, deviations and/or breaches in key areas are reviewed and a decision is rendered on any adjustments through a formalized process of S&T governance.

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | | DATE: March 2013 |
|---|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>307B: *Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (Budgeted) (AF)* | |

| COST ($ in Millions) | All Prior Years | FY 2012 | FY 2013# | FY 2014 Base | FY 2014 OCO ## | FY 2014 Total | FY 2015 | FY 2016 | FY 2017 | FY 2018 | Cost To Complete | Total Cost |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 307B: *Force Health Protection, Advanced Diagnostics/ Therapeutics Research & Development (Budgeted) (AF)* | - | 14.335 | 12.120 | 15.796 | - | 15.796 | 16.648 | 17.852 | 18.991 | 19.333 | Continuing | Continuing |

# FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

## The FY 2014 OCO Request will be submitted at a later date

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

This project area seeks to deliver an improved Force Health Protection capability across the full spectrum of operations. Under Force Health Protection, sub-project areas include: Directed Energy and Occupational and Environmental Health. Research in the Directed Energy sub-project area seeks to develop technologies to "detect to warn" and "detect to protect" AF operators such that they can take appropriate actions to prevent or minimize exposure leading to adverse health effects. Research in the Occupational and Environmental Health sub-project area involves the assessment and implementation of innovative new technologies that not only give Air Force Medical Service personnel battlefield situational awareness of Occupational and Environmental Health Hazards, but which also enables effective surveillance, detection and mitigation. Other areas of interest include infectious disease and food and water surveillance. Under Advanced Diagnostics/Therapeutics Research and Development, sub-project areas include Personalized Medicine/Genomic Medicine and the Simple Situational Awareness Widget. The Personalized Medicine/Genomic Medicine sub-project area supports the development of systems advancing the delivery of 'Omic-informed personalized medicine and emphasizes targeted prevention, diagnosis, and treatment. The field of 'Omic medicine includes genomics, epigenetics, transcriptomics, proteomics, metabolomics, and gene-environment interaction. The delivery of pro-active, evidence-based, personalized medicine will improve health in warfighters and beneficiaries by providing care that is specific to the situation and patient, to include preventing disease or injury, early and accurate diagnosis, and selection of appropriate and effective treatment. Personalized medicine will reduce morbidity, mortality, mission impact of illness/injury, and healthcare costs while increasing health and wellness of the AF population and efficiency of the healthcare system. This supports systems development in multiple focus areas.

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2012 | FY 2013 | FY 2014 |
|---|---|---|---|
| ***Title:*** Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (Budgeted) (Air Force) | 14.335 | 12.120 | 15.796 |
| ***Description:*** This project area seeks to deliver an improved Force Health Protection capability across the full spectrum of operations. Under Force Health Protection, sub-project areas include: Directed Energy and Occupational and Environmental Health. Research in the Directed Energy sub-project area seeks to develop technologies to "detect to warn" and "detect to protect" AF operators such that they can take appropriate actions to prevent or minimize exposure leading to adverse health effects. Research in the Occupational and Environmental Health sub-project area involves the assessment and implementation of innovative new technologies that not only give Air Force Medical Service personnel battlefield situational awareness of Occupational and Environmental Health Hazards, but which also enables effective surveillance, detection and mitigation. Other | | | |

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | DATE: March 2013 |
|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>307B: *Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (Budgeted) (AF)* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2012 | FY 2013 | FY 2014 |
|---|---|---|---|

areas of interest include infectious disease and food and water surveillance. Under Advanced Diagnostics/Therapeutics Research and Development, sub-project areas include Personalized Medicine/Genomic Medicine and the Simple Situational Awareness Widget. The Personalized Medicine/Genomic Medicine sub-project area supports the development of systems advancing the delivery of 'Omic-informed personalized medicine and emphasizes targeted prevention, diagnosis, and treatment. The field of 'Omic medicine includes genomics, epigenetics, transcriptomics, proteomics, metabolomics, and gene-environment interaction. The delivery of pro-active, evidence-based, personalized medicine will improve health in warfighters and beneficiaries by providing care that is specific to the situation and patient, to include preventing disease or injury, early and accurate diagnosis, and selection of appropriate and effective treatment. Personalized medicine will reduce morbidity, mortality, mission impact of illness/injury, and healthcare costs while increasing health and wellness of the AF population and efficiency of the healthcare system. This supports systems development in multiple focus areas.

***FY 2012 Accomplishments:***

Demonstrated that inhalation exposure to jet fuel (JP-8) concurrent with noise exposure can impair hearing at noise levels less than occupational exposure levels; initiated studies of other fuel types. Completed studies supporting the development of an in vitro Toxicity Screening Battery to evaluate occupational health risks associated with jet fuel exposure. Established methods to characterize the properties of nanomaterials that are linked to cellular toxicity. Built a nanomaterial exposure chamber prototype for testing occupational airborne exposures.

Completed assessment of the impact of laser exposure to the eye; identified a panel of proteins associated with retinal damage. Performed pilot study on the molecular bioeffects of high power microwave exposure.

Developed prototype devices to locate laser energy sources, generate data on the laser parameters, and analyze the data in order to characterize the associated health risk. Continued investigation on smaller/more capable sensors for remote environmental and physiological monitoring. Initiated research on vests to prevent heat stress in extreme environments. Assessed emissions from waste incineration/burnpits; used data to improve predictive models for human exposure from the dispersion of environmental contaminants. Initiated development of technology and methods to analyze soil samples for radionuclide presence to support AF Radiologic Assessment Team, whose mission is DoD-unique. Assessed commercially available Aircrew Ballistic Protective Eyewear for operational use. Initiated research to develop miniaturized sensors to identify hypoxic/toxic aircrew environments. Oversaw operator evaluation of individual blast gauges in a deployed environment. Added four pathogens to the Film Array viral respiratory pathogen test panel and achieved FDA clearance.

***FY 2013 Plans:***

Complete follow-on studies assessing the relationship between inhalation exposure to alternative jet fuels and noise. Using the nanomaterial exposure chamber prototype, test scenarios for testing occupational airborne exposures. Use the panel of proteins identified in laser exposure studies to characterize retinal laser injuries. Expand study of high-powered microwave exposures

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | DATE: March 2013 |
|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>307B: *Force Health Protection, Advanced Diagnostics/Therapeutics Research & Development (Budgeted) (AF)* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2012 | FY 2013 | FY 2014 |
|---|---|---|---|
| to establish dose-response relationships. Further evaluate the prototype devices to locate laser energy sources against additional laser challenges. Perform field testing of smaller/more capable sensors for remote environmental and physiological monitoring. Continue to evaluate vests to prevent heat stress in extreme environments in field conditions. Complete development of technology and methods to analyze soil samples for radionuclide presence and transition to AF Radiologic Assessment Team, whose mission is DoD-unique. Recommend, to the line of the Air Force, a list of commercially available Aircrew Ballistic Protective Eyewear for use in operational environments. Continue research to develop miniaturized sensors to identify hypoxic/ toxic aircrew environments.<br>***FY 2014 Plans:***<br>Develop a retinal injury atlas database for use by clinicians, and further apply data to perform a bioinformatics-based analysis of retinal injury treatment alternatives. Integrate the health risk assessments produced from the prototype devices to locate laser energy sources into command and control. Work with MAJCOMS to test smaller/more capable sensors for remote environmental and physiological monitoring in an operational setting. Apply smaller/more capable sensors to enable data transfer. Test miniaturized sensors to identify hypoxic/toxic aircrew environments in representative environments. | | | |
| **Accomplishments/Planned Programs Subtotals** | 14.335 | 12.120 | 15.796 |

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

N/A

**Remarks**

**D. Acquisition Strategy**

Broad Area Announcement (BAA) and Intramural calls for proposal are used to award initiatives in this program and project following determinations of scientific and technical merit, validation of need, prioritization, selection and any necessary legal and/or regulatory approvals (IRB, etc)

**E. Performance Metrics**

Individual initiatives are measured through a quarterly annual project performance reporting system and program management review process -- performance is measured against standardized criteria for cost, schedule and performance (technical objectives) and key performance parameters. Variances, deviations and/or breaches in key areas are reviewed and a decision is rendered on any adjustments through a formalized process of S&T governance.

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | | DATE: March 2013 |
|---|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>308B: *Expeditionary Medicine Research & Development (Budgeted) (AF)* | |

| COST ($ in Millions) | All Prior Years | FY 2012 | FY 2013# | FY 2014 Base | FY 2014 OCO ## | FY 2014 Total | FY 2015 | FY 2016 | FY 2017 | FY 2018 | Cost To Complete | Total Cost |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 308B: *Expeditionary Medicine Research & Development (Budgeted) (AF)* | - | 2.796 | 5.736 | 4.906 | - | 4.906 | 6.229 | 5.271 | 4.474 | 4.554 | Continuing | Continuing |

# FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

## The FY 2014 OCO Request will be submitted at a later date

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

This project area identifies cutting edge techniques and technologies that can be employed by AF medics during contingency operations. Sub-project areas include: Expeditionary Logistics and Expeditionary Casualty Care. Expeditionary Logistics seeks to develop/validate novel procedures, materials, techniques, and tools to reduce size and weight, optimize power requirements, and minimize logistics footprint associated with expeditionary operations. It also examines ways to standardize equipment and supplies used by medical response teams because of the increasing number of missions that find teams from different countries working together. Expeditionary Casualty Care focuses on optimizing existing and developing new casualty care tools and techniques, improving methods and techniques for remote monitoring and triage systems, identifying and mitigating issues related to casualty care in an expeditionary setting, and validation of best-fit technologies in casualty care missions.

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2012 | FY 2013 | FY 2014 |
|---|---|---|---|
| ***Title:*** Expeditionary Medicine Research & Development (Air Force) | 2.796 | 5.736 | 4.906 |

***Description:*** This project area identifies cutting edge techniques and technologies that can be employed by AF medics during contingency operations. Sub-project areas include: Expeditionary Logistics and Expeditionary Casualty Care. Expeditionary Logistics seeks to develop/validate novel procedures, materials, techniques, and tools to reduce size and weight, optimize power requirements, and minimize logistics footprint associated with expeditionary operations. It also examines ways to standardize equipment and supplies used by medical response teams because of the increasing number of missions that find teams from different countries working together. Expeditionary Casualty Care focuses on optimizing existing and developing new casualty care tools and techniques, improving methods and techniques for remote monitoring and triage systems, identifying and mitigating issues related to casualty care in an expeditionary setting, and validation of best-fit technologies in casualty care missions.

***FY 2012 Accomplishments:***

Supported the development of a next-generation Trauma Specific Vascular Shunt prototype for submission through the FDA approval process. Completed Congressional project to develop a prototype laser device for hemorrhage control and tissue cutting. Completed a Congressionally funded project to develop a Virtual Medical Training program for C-17 loading and unloading, and transitioned it to Air Mobility Command. In conjunction with the Enroute Care Thrust area, completed draft Capability Development Document for multi-channel negative pressure wound treatment system, and addressed advanced development

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | DATE: March 2013 |
|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>308B: *Expeditionary Medicine Research & Development (Budgeted) (AF)* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2012 | FY 2013 | FY 2014 |
|---|---|---|---|
| issues. Continued research on the development of algorithms for the continuous non-invasive monitoring of patient status in order to predict actionable interventions. Initiated research on a novel technique for infection control of traumatic wounds, predicting blood needs using pre-hospital vital signs, and hemorrhagic shock resuscitation.<br>***FY 2013 Plans:***<br>Complete the FDA approval process for the Trauma Specific Vascular Shunt, transition the device, and proceed to fielding and procurement. Apply predictive algorithms for the continuous non-invasive monitoring of patient status in order to predict actionable interventions. Evaluate clinical utility of prototype laser device for hemorrhage control and tissue cutting. Continue research on a novel technique for infection control of traumatic wounds, predicting blood needs using pre-hospital vital signs, and hemorrhagic shock resuscitation. Pursue additional research to mature the multi-channel negative pressure wound treatment system and continue to address advanced development issues.<br>***FY 2014 Plans:***<br>Initiate research on therapeutic drugs given by first responders to slow body functions providing more time to transfer of seriously wounded to definitive care. Continue research addressing needs related to Expeditionary Casualty Care. | | | |
| **Accomplishments/Planned Programs Subtotals** | 2.796 | 5.736 | 4.906 |

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

N/A

**Remarks**

**D. Acquisition Strategy**

Broad Area Announcement (BAA) and Intramural calls for proposal are used to award initiatives in this program and project following determinations of scientific and technical merit, validation of need, prioritization, selection and any necessary legal and/or regulatory approvals (IRB, etc)

**E. Performance Metrics**

Individual initiatives are measured through a quarterly annual project performance reporting system and program management review process -- performance is measured against standardized criteria for cost, schedule and performance (technical objectives) and key performance parameters. Variances, deviations and/or breaches in key areas are reviewed and a decision is rendered on any adjustments through a formalized process of S&T governance.

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | | DATE: March 2013 |
|---|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>309A: *Regenerative Medicine (USUHS)* | |

| COST ($ in Millions) | All Prior Years | FY 2012 | FY 2013# | FY 2014 Base | FY 2014 OCO ## | FY 2014 Total | FY 2015 | FY 2016 | FY 2017 | FY 2018 | Cost To Complete | Total Cost |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 309A: *Regenerative Medicine (USUHS)* | - | 6.877 | 7.365 | 7.504 | - | 7.504 | 7.657 | 7.929 | 8.062 | 8.207 | Continuing | Continuing |

# FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

## The FY 2014 OCO Request will be submitted at a later date

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

For the Uniformed Services University of the Health Sciences (USUHS), the Center for Neuroscience and Regenerative Medicine (CNRM) brings together the expertise of clinicians and scientists across disciplines to catalyze innovative approaches to traumatic brain injury (TBI) research. CNRM Research Programs emphasize aspects of high relevance to military populations, with a primary focus on patients at the Walter Reed National Military Medical Center.

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2012 | FY 2013 | FY 2014 |
|---|---|---|---|
| ***Title:*** Regenerative Medicine (USUHS) | 6.877 | 7.365 | 7.504 |

***Description:*** The Center for Neuroscience and Regenerative Medicine (CNRM) brings together the expertise of clinicians and scientists across disciplines to catalyze innovative approaches to traumatic brain injury (TBI) research. CNRM Research Programs emphasize aspects of high relevance to military populations, with a primary focus on patients at the Walter Reed National Military Medical Center.

***FY 2012 Accomplishments:***

The CNRM research program is comprised of over 200 investigators that have primary appointments in 16 different academic departments of USUHS, the NIH Clinical Center, seven NIH Institutes, and multiple clinical departments at WRNMMC. The CNRM has established 11 research cores, with the addition of the new Acute Studies Core in 2012.

- An Acute Studies core was developed to focus efforts that had been ongoing at local civilian hospitals for neuroimaging and biomarkers analyses at early time points post-injury that cannot be recruited at NIH or WRNMMC. These early clinical interactions are also directly connected to longitudinal follow up at the NIH CC with potential for recruitment into other CNRM studies.
- The Recruitment and Phenotyping Cores were reorganized for more effective interactions with military sites and to serve as an early clinical interface that supports civilian patient recruitment into CNRM studies at the NIH.
- The Human Imaging core and Image Processing core have been developing scanning protocols for use of the human 3T molecularMR, which was installed in November 2011. This Siemens Biograph mMR system enables simultaneous MR and PET imaging and is one of the first systems in the US with this unique capability.

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | DATE: March 2013 |
|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>309A: *Regenerative Medicine (USUHS)* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2012 | FY 2013 | FY 2014 |
|---|---|---|---|
| - The Translational Imaging core has been developing novel scanning protocols for rodent microPET, microCT, and 7T MR, especially as relevant to specialized needs for TBI pathologies and with consideration of comparison with the human scanning applications.<br>- The Pre-clinical (Rodent Surgical and Behavioral) Cores use is heavily subscribed. Efforts are ongoing to provide a state-of-the-art blast facility for animal model testing at USU.<br>- The Neuropathology core has developed capabilities for human brain tissue banking to characterize military TBI and associated cases.<br>- The Informatics core has developed the database and policies for CNRM human subjects research that is aligned with the efforts across federal agencies for data acquisition using common data elements acquisition and for data storage in a federal TBI database.<br><br>CNRM received 69 proposals in response to a FY12 proposal call. After external scientific review and approval by the Programmatic Oversight Committee, 16 two-year projects were funded for FY12.<br><br>The CNRM has 27 approved human use protocols at 10 different sites, including a biorepository and informatics warehouse and both military and civilian parallel natural history studies, and 30 approved animal use protocols.<br>***FY 2013 Plans:***<br>CNRM will accomplish several key objectives in FY13: (1) Fund start-up research of 1-4 new faculty members; (2) Increase innovative human imaging capability at the new WRNMMC campus; (3) Continue operational capability of all Cores and provide a sound research infrastructure; (4) Approve an additional 10 – 15 human use and animal use protocols to move forward beyond the existing research directions; and (5) Obtain data to address the current needs of the medical community to better diagnose and intervene for the prevention of the long term consequences resulting from traumatic brain injury (TBI).<br>***FY 2014 Plans:***<br>CNRM will accomplish several key objectives in FY14: (1) Fund start-up research of 1-4 new faculty members; (2) Fund new research projects through a call for proposals; (3) Continue operational capability of all Cores and provide a sound research infrastructure; (4) Approve an additional 10 – 15 human use and animal use protocols to move forward beyond the existing research directions; and (5) Obtain data to address the current needs of the medical community to better diagnose and intervene for the prevention of the long term consequences resulting from traumatic brain injury (TBI). | | | |
| **Accomplishments/Planned Programs Subtotals** | 6.877 | 7.365 | 7.504 |

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | DATE: March 2013 |
|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>309A: *Regenerative Medicine (USUHS)* |

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

| Line Item | FY 2012 | FY 2013 | FY 2014 Base | FY 2014 OCO | FY 2014 Total | FY 2015 | FY 2016 | FY 2017 | FY 2018 | Cost To Complete | Total Cost |
|---|---|---|---|---|---|---|---|---|---|---|---|
| • BA-1, 0806721HP: *Uniformed Services University of the Health Sciences* | 8.244 | 8.495 | 8.755 | | 8.755 | 9.022 | 9.293 | 9.395 | 9.555 | Continuing | Continuing |

**Remarks**

**D. Acquisition Strategy**

N/A

**E. Performance Metrics**

Center for Neuroscience and Regenerative Medicine: In FY12 through FY14, identify, design protocols, perform scientific and program reviews, and conduct research in Clinical Core activities such as Phenotyping, Imaging and Imaging Analysis, to aid in patient diagnosis and evaluation.

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | | DATE: March 2013 |
|---|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>373A: *GDF - Medical Technology Development* | |

| COST ($ in Millions) | All Prior Years | FY 2012 | FY 2013# | FY 2014 Base | FY 2014 OCO ## | FY 2014 Total | FY 2015 | FY 2016 | FY 2017 | FY 2018 | Cost To Complete | Total Cost |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 373A: *GDF - Medical Technology Development* | - | 48.595 | 107.248 | 150.166 | - | 150.166 | 161.729 | 161.320 | 160.683 | 163.575 | Continuing | Continuing |

# FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

## The FY 2014 OCO Request will be submitted at a later date

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

Guidance for Development of the Force - Medical Technology Development provides funds for promising candidate solutions that are selected for initial safety and effectiveness testing in animal studies and/or small scale human clinical trials regulated by the US Food and Drug Administration prior to licensing for human use. Research in this PE is designed to address the following: areas of interest to the Secretary of Defense regarding Wounded Warriors, capabilities identified through the Joint Capabilities Integration and Development System, and the strategy and initiatives described in the Quadrennial Defense Review. Program development and execution is peer-reviewed and fully coordinated with all of the Military Services, appropriate Defense Agencies or Activities and other federal agencies, to include the Department of Veterans Affairs, the Department of Health and Human Services, and the Department of Homeland Security. This coordination occurs through the planning and execution activities of the Joint Program Committees (JPCs), established for the Defense Health Program, Research Development Test and Evaluation (RDT&E) funding. Research supported by this PE includes polytrauma and blast injury, diagnosis and treatment of brain injury, environmental health and performance, physiological and psychological health, injury prevention and reduction, medical simulation and training, health informatics, and rehabilitation.

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2012 | FY 2013 | FY 2014 |
|---|---|---|---|
| ***Title:*** GDF – Medical Technology Development | 48.595 | 107.248 | 150.166 |
| ***Description:*** Funds provide for the development of medical technology candidate solutions and components of early prototype systems for test and evaluation. Promising drug and vaccine candidates, knowledge products, and medical devices and technologies are selected for initial safety and effectiveness testing in small scale human clinical trials. | | | |
| ***FY 2012 Accomplishments:***<br>FY 2012 Accomplishments:<br>The most promising technologies arising from the FY11 investment were continued into FY12 and considered for transition to a higher budget activity. | | | |
| Medical training and health information systems aimed to improve healthcare access, availability, continuity, cost effectiveness, and quality. Medical simulation and training efforts have focused on understanding how cognitive and psychomotor skills of healthcare personnel deteriorate and how this can be minimized using a data driven predictive model. Efforts also included out-patient and home rehabilitation and educational simulation technologies specifically for the wounded service members. The | | | |

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | DATE: March 2013 |
|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>373A: *GDF - Medical Technology Development* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2012 | FY 2013 | FY 2014 |
|---|---|---|---|
| Health Information Technology Committee utilized prototype and strategic projects in order to mature efforts within the focus areas of force health protection and readiness, medical resourcing, healthcare services, and enterprise infrastructure management.<br><br>For military infectious diseases research, the most promising efforts initiated under Applied Research in FY10 and FY11 transitioned to Medical Technology Development. Areas of research included antibacterial and anti-biofilm agents, biomarker and diagnostic assay technologies for wound infection, detection of multidrug-resistant organisms (MDROs) in wound infection prevention and management, and antimicrobial countermeasures.<br><br>The military operational medicine efforts are aimed to: determine if administration of an antioxidant can protect against noise-induced hearing loss; integrate the surface mounted clay add-on device prototype into current software that will improve the method for evaluating body armor's protective effectiveness against blunt trauma; determine the impact of load carriage and grade on the energy consumed by individual muscles during locomotion and identify models that predict the energy consumed with and without load carriage; develop and validate self-reporting instruments to assess psychological attributes and constructs of Soldier performance, mental strength and psychological well-being; develop surveys to delineate relationship factors that contribute to the longitudinal progression of combat-related PTSD and enhanced suicide; develop individualized models that will allow for the prediction of the effects of chronic sleep restriction on cognitive performance; and develop models that predict the effects of caffeine in mitigating performance impairment during sleep deprivation.<br><br>For combat casualty care research, the program conducted studies of enhanced oxygen delivery in acute spinal cord injury that involves analyzing immunohistochemicals (a test that shows specific antigens in tissues by the use of markers that are either fluorescent dyes or enzymes) in spinal cord tissue; a plasma volume expander study looks for toxicity and pharmacokinetics (a branch of pharmacology dedicated to the determination of the fate of substances administered externally to a living organism); and red blood cell storage research examined the effects of storage time increases on the risk of microchimerism (presence of a small number of cells that originate from another individual and therefore genetically distinct from the cells of the host individual). The military medical photonics and smooth-pursuit eye tracking (Eye TRAC) technologies were further developed. A new program announcement was published and research was started in the areas of the control of internal bleeding using catheters, and the effect of perfluorocarbons (chemically reactive compounds composed of carbon and fluorine) used for resuscitation on the body's blood to clot effectively.<br><br>Clinical and rehabilitative medicine performed studies in the areas of neuromusculoskeletal injury, regenerative medicine and sensory system traumatic injury, including vision, hearing and balance restoration. | | | |
| ***FY 2013 Plans:*** | | | |

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | DATE: March 2013 |
|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>373A: *GDF - Medical Technology Development* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2012 | FY 2013 | FY 2014 |
|---|---|---|---|
| Medical training and health information systems are improving healthcare access, availability, continuity, cost effectiveness, and quality. Specific efforts focus on research investigating the utility of augmented reality training tools towards military healthcare personnel, specifically comparing training techniques that use current training methods versus augmented reality methods. Continue efforts in out-patient or home rehabilitation and educational simulation technologies for the wounded service member Research efforts are exploring emerging technologies to mitigate enterprise risk within health informatics, force health protection and readiness, medical resourcing, healthcare services, and enterprise infrastructure management.<br><br>For military infectious diseases research, multi-year, first-in-human studies, started during FY11/12, in wound infection prevention and management and antimicrobial countermeasures for antibacterial and/or anti-biofilm agents, biomarker and diagnostic assay technologies for wound infection, and detection of multidrug-resistant organisms (MDROs) will be supported toward down selection and transition into Medical Product Support and Advanced Concept Development. New Medical Technology Development proposals will be supported in rapid screening of fresh whole blood for pathogens, wound infection prevention and management, and antimicrobial countermeasures.<br><br>Military operational medicine efforts are validating dose response curves for noise induced hearing loss, using animal models to determine protective capabilities within the inner ear using antioxidants and determine the most effective doses and maximum time delays to prevent noise induced hearing loss. This information will result in significant reductions in noise related compensation claims to the Department of Veterans Administration and facilitate the return-to-duty for injured Warfighters. Specific efforts are validating the performance of the surface mounted clay add-on device using live-fire tests of military grade armor systems providing the first biomedically valid behind-body-armor design standard as a replacement to the current Department of Justice standard. This will allow equipment developers to design body armor appropriate to the specific needs of each region of the body. Other efforts entail conducting human clinical trials of the Hydration Status Monitor for diagnostic and biological testing, a device to monitor fluid intake and electrolyte imbalance; field studies to determine the effect of vitamin D and calcium supplements on nutritional status of Warfighters leading to improved bone health and mitigating the potential for bone stress fractures; validating constructs of Warfighters performance, mental strength and psychological well-being using current psychological assessment tools providing a validated portfolio of self-reporting instruments capable of assessing various psychological attributes of military personnel, thereby enhancing psychological resilience.<br><br>Combat casualty care research is pursuing successful studies, from FY11 and 12, such as the study of enhanced oxygen delivery of oxygen in acute spinal cord injury, the plasma volume expander, red blood cell storage research and will start technology development of platelet-derived agents to stop bleeding and neuromodulation for the repair of traumatic injuries to the brain, and will issue a program announcement in the areas of enroute care and forward surgical and intensive battlefield care. | | | |

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | DATE: March 2013 |
|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>373A: *GDF - Medical Technology Development* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2012 | FY 2013 | FY 2014 |
|---|---|---|---|
| Clinical and rehabilitative medicine is advancing studies in neuromusculoskeletal injury rehabilitation, pain management, and sensory system restoration and rehabilitation after traumatic injury. We are initiating studies to support development and preclinical and pilot/early phase clinical evaluations of candidate technologies for restoration and rehabilitation strategies and medical products. Specific focus areas include neuromusculoskeletal injury rehabilitation strategies and devices, prosthetics, and the prevention of heterotopic ossification (bone formation in soft tissue following injury); novel therapeutics and devices for pain management; regenerative medicine-based approaches for limb and digit salvage, craniomaxillofacial (skull, face and jaw) reconstruction, scarless wound healing, burn repair, genitourinary restoration and addressing compartment syndrome (muscle, nerve and vascular damage due to swelling post-injury); restoration and rehabilitation of sensory system injury, including vision, hearing and balance injury and dysfunction. | | | |
| ***FY 2014 Plans:***<br>Medical Training and Health Information Sciences will continuework in two primary research portfolios: Medical Simulation and Training, and Health Informatics & Information Technology. Medical Simulation and Training will primarily focus on follow up research opportunities identified by the Combat Casualty Training Consortium (CCTC), which is identifying potential gaps where simulation technology can be utilized in combat medic training with the impact of reducing live tissue training. Specific emphasis is on how nano-technologies may improve sensors, haptics (touch feedback), actuators, and tissue fluidics integrated into simulation training systems. Medical Practice Initiative efforts are aimed at understanding healthcare personnel skill decay through improved data mining and its correlation with skill. Health Informatics & Information Technology looks to conduct research on risk reduction within the Military Health System to identify ways to reduce potential near- and long-term cost of IT technology and systems, as well as the transition of a joint Department of Veterans Affairs (VA) and Department of Defense (DOD) integrated Electronic Health Record (iEHR).<br><br>The military infectious diseases research program will continue the multi-year, first in human studies started in FY12 in the Wound Infection Prevention and Management and Antimicrobial Countermeasures Programs. Successful Applied Biomedical Technology funded projects will be added to the Medical Technology Development portfolio to further advance the product towards commercialization. A new program announcement is expected for Wound Infection Prevention and Management based on an ongoing gap analysis.<br><br>Military operational medicine research will continue medical technology development efforts initiated in FY12 and FY13 in nutrition and dietary supplements, warfighter performance and sustainment in extreme environments (such as extreme heat, cold, or altitude), establishment of return to duty/medical standards criteria, blast injury models and performance standards for protections systems, diagnostics and metrics for hearing loss and protection, alcohol and substance abuse, diagnosis and treatment of deployment-related psychological health problems, diagnosis and treatment of PTSD, military family and warfighter resilience, suicide prevention, pulmonary health in the deployed environment, and blast exposure during breaching. The Military Operational | | | |

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | DATE: March 2013 |
|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>373A: *GDF - Medical Technology Development* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2012 | FY 2013 | FY 2014 |
|---|---|---|---|
| Medicine Joint Program Committee will issue program announcements with topics in the areas of physiological health, injury prevention and reduction, psychological health, and environmental health and protection.<br><br>Combat casualty care research will pursue successful studies from FY12 and 13, such as the study of enhanced oxygen delivery of oxygen in acute spinal cord injury, the plasma volume expander, red blood cell storage research, platelet-derived agents to stop bleeding and neuromodulation, and will start technology development of agents to improve resuscitation after severe bleeding, foams to stop internal bleeding, and real-time, physiologic monitoring across the battlespace.<br><br>Clinical and rehabilitative medicine will continue advancing studies in neuromusculoskeletal injury rehabilitation, pain management, and sensory system restoration and rehabilitation after traumatic injury. Clinical and rehabilitative medicine will continue studies started in FY13 to support development and preclinical and pilot/early phase clinical evaluations of candidate technologies for restoration and rehabilitation strategies and medical products. Specific focus areas include: neuromusculoskeletal injury rehabilitation strategies and devices; prosthetics; neural interfaces (electrodes wired into the brain) and the prevention of heterotopic ossification (bone formation in soft tissue following injury); novel therapeutics and devices for pain management; regenerative medicine-based approaches for limb and digit salvage; craniomaxillofacial (skull, face and jaw) reconstruction; scarless wound healing; burn repair; genitourinary restoration and addressing compartment syndrome (muscle, nerve and vascular damage due to swelling post-injury); and restoration and rehabilitation of sensory system injury, including vision, hearing and balance injury and dysfunction. | | | |
| **Accomplishments/Planned Programs Subtotals** | 48.595 | 107.248 | 150.166 |

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

N/A

**Remarks**

**D. Acquisition Strategy**

Mature and demonstrate safety and effectiveness of medical procedures, medical devices, and drug and vaccine candidates intended to prevent or minimize effects from battlefield injuries, diseases, and extreme or hazardous environments. Milestone A packages will be developed to transition promising products into advanced development.

**E. Performance Metrics**

Principal investigators will participate in In-Progress Reviews, high-level DHP-sponsored review and analysis meetings, submit quarterly and annual status reports, and are subjected to Program Office and/or Program Sponsor Representative progress reviews to ensure that milestones are being met and deliverables will be transitioned

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | DATE: March 2013 |
|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>373A: *GDF - Medical Technology Development* |

on schedule. The benchmark performance metric for transition of research conducted with GDF-Medical Technology Development funding will be the attainment of maturity level that is typical of Technology Readiness Level 6 or the equivalent for knowledge products.

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | | DATE: March 2013 |
|---|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>378A: *CoE-Breast Cancer Center of Excellence (Army)* | |

| COST ($ in Millions) | All Prior Years | FY 2012 | FY 2013# | FY 2014 Base | FY 2014 OCO ## | FY 2014 Total | FY 2015 | FY 2016 | FY 2017 | FY 2018 | Cost To Complete | Total Cost |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 378A: *CoE-Breast Cancer Center of Excellence (Army)* | - | 9.722 | 10.458 | 10.636 | - | 10.636 | 10.830 | 11.229 | 11.418 | 11.624 | Continuing | Continuing |

# FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

## The FY 2014 OCO Request will be submitted at a later date

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

The Breast Cancer CoE (Army) provides a multidisciplinary approach as the standard of care for treating breast diseases and breast cancer. This approach integrates prevention, screening, diagnosis, treatment and continuing care, incorporation of advances in risk reduction, biomedical informatics, tissue banking and translational research. The project is based on a discovery science paradigm, leveraging high-throughput molecular biology technology and our unique clinically well-characterized tissue repository with advances in biomedical informatics leading to hypothesis-generating discoveries that are then tested in hypothesis-driven experiments. The objective of this research is to reduce the incidence, morbidity (illness), and mortality (death) of breast diseases and breast cancer among all military beneficiaries.

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2012 | FY 2013 | FY 2014 |
|---|---|---|---|
| ***Title:*** Breast Cancer Center of Excellence | 9.722 | 10.458 | 10.636 |
| ***Description:*** Provides a multidisciplinary approach as the standard of care for treating breast diseases and breast cancer. | | | |
| ***FY 2012 Accomplishments:***<br>The Breast Cancer CoE (Army), also referred to as the Clinical Breast Care Project (CBCP), relocated in FY12 to the new Walter Reed National Military Medical Center Bethesda (WRNMMC-B) campus as our main military site, accruing over 800 subjects annually to the "core" CBCP protocols. The CBCP acquired through consented protocol acquisitions, over 7,000 specimens (neoplastic and non-neoplastic breast tissues and tumors, lymph nodes, metastatic deposits, blood and its components, bone marrow) on subjects with all types of breast diseases and cancer. The repository is utilized as the basis for all molecular analyses in CBCP labs, as outlined in the CBCP Core Protocols allowing for global expression analysis of the DNA, RNA, and Protein features and as the basis for intramural and extramural collaborations for secondary usage research. CBCP planned to: perform whole genome DNA sequencing on DNA from 60 cases of breast cancer; continued development of and support of a robust laboratory information management system to ensure proper tracking of data acquisition and a clinically relevant and laboratory research-linked prospective, longitudinal computerized data warehouse to support translational research and ultimately support physician decision making; continued development of an analytical system for integrative data analysis and mining, and further refined a breast knowledge base to support clinical and research activities in BC-COE; utilized Clinical Laboratory Workflow System as the data analysis tool and integrated AHLTA data from the military's main electronic medical record; identified and counseled 260 patients at high risk for development of breast cancer, and employed risk reduction strategies; performed targeted | | | |

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | DATE: March 2013 |
|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>378A: *CoE-Breast Cancer Center of Excellence (Army)* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2012 | FY 2013 | FY 2014 |
|---|---|---|---|
| research by conducting DNA and Protein analysis of Stages I, II, and III breast cancer, cancer found in the breast ducts and lobules, and pre-malignant breast lesions; and presented findings in peer-reviewed publications and at national meetings.<br>***FY 2013 Plans:***<br>In FY13, the Breast Cancer CoE, also referred to as the Clinical Breast Care Project (CBCP), will enroll subjects seen at the Breast Translational Research Center in the "core" CBCP protocols. The CBCP will acquire specimens according to approved research protocols, and conduct analyses that will include but not be limited to: risk factors for developing breast cancer, effectiveness of various modalities of treatment, and actual risk of developing cancer. The CBCP will enhance the acquisition and banking of breast tissue, lymph nodes, serum/plasma and other blood derivatives from informed and consented donors to be the foundation for their translational research program. Initiatives within the translational research program include generation of a complete genomic DNA sequence from up to 60 breast cancer cases and utilization of antibody tissue staining and analysis to generate clinically relevant profiles of breast tumors to better stratify the disease in terms of prognosis and treatment options. The Biomedical Informatics Group will support the research activities of the Center as well as carry out research into new algorithms and methods to improve the detection and treatment of breast cancer.<br>***FY 2014 Plans:***<br>In FY 14, the Breast Cancer CoE (Army), also referred to as the Clinical Breast Care Project (CBCP), at Walter Reed National Military Medical Center (WRNMMC) Bethesda will continue to accrue subjects annually to the "core" CBCP protocols. The CBCP will continue to acquire, through consented protocol specimens (normal and abnormal breast tissues and tumors, lymph nodes, metastatic deposits, blood and its components, bone marrow) annually from subjects with all types of breast diseases and cancer. The repository will continue to be utilized as the basis for all molecular analyses in CBCP labs, as outlined in the CBCP Core Protocols allowing for global expression analysis of the DNA, RNA, and protein features and as the basis for intramural and extramural collaborations for secondary usage research. CBCP plans to perform whole genome DNA sequencing on DNA from 60 cases of breast cancer; continue the development of and support of a robust laboratory information management system to ensure proper tracking of data acquisition and a clinically relevant and laboratory research-linked prospective, longitudinal computerized data warehouse to support translational research and ultimately support physician decision making; continue development of an analytical system for integrative data analysis and mining, and further refine a breast knowledge base to support research activities in CBCP; utilizing Clinical Laboratory Workflow System as the data analysis tool and integrating AHLTA data from the military's main electronic medical record; identify research subjects at high risk for development of breast cancer, and employ risk reduction strategies; complete genomic and proteomic analysis of samples collected at various developmental stages of breast cancer, and present findings in peer-reviewed publications and at national meetings. | | | |
| **Accomplishments/Planned Programs Subtotals** | 9.722 | 10.458 | 10.636 |

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | DATE: March 2013 |
|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>378A: *CoE-Breast Cancer Center of Excellence (Army)* |

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

N/A

**Remarks**

**D. Acquisition Strategy**

N/A

**E. Performance Metrics**

Performance is judged on the number of active protocols, the number of articles that appear in peer-reviewed journals, and the number of contact hours in support of the training of residents and fellows in the Military Health System.

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | | DATE: March 2013 |
|---|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>379A: *CoE-Gynecological Cancer Center of Excellence (Army)* | |

| COST ($ in Millions) | All Prior Years | FY 2012 | FY 2013# | FY 2014 Base | FY 2014 OCO ## | FY 2014 Total | FY 2015 | FY 2016 | FY 2017 | FY 2018 | Cost To Complete | Total Cost |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 379A: *CoE-Gynecological Cancer Center of Excellence (Army)* | - | 8.494 | 9.138 | 9.293 | - | 9.293 | 9.463 | 9.811 | 9.977 | 10.157 | Continuing | Continuing |

# FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

## The FY 2014 OCO Request will be submitted at a later date

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

The Gynecologic Cancer Center of Excellence (Army) focuses on characterizing the molecular alterations associated with benign and malignant gynecologic disease and facilitates the development of novel early detection, prevention and novel biologic therapeutics for the management of gynecologic disease. The objective of this research is to reduce the incidence, morbidity (illness), and mortality (death) of gynecologic diseases among all military beneficiaries.

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2012 | FY 2013 | FY 2014 |
|---|---|---|---|
| ***Title:*** Gynecologic Cancer Center of Excellence (Army) | 8.494 | 9.138 | 9.293 |

***Description:*** The Gynecologic Cancer Center of Excellence focuses on characterizing the molecular alterations associated with benign and malignant gynecologic disease and facilitates the development of novel early detection, prevention and novel biologic therapeutics for the management of gynecologic disease.

***FY 2012 Accomplishments:***

For FY12, the Gynecologic Cancer Center of Excellence is externally validating the expression profiles associated with poor prognosis in endometrial cancer using independent retrospectively and prospectively collected sample sets. Discovery work in both endometrial and ovarian cancer integrated data from DNA, RNA, and protein studies is intended to correlate molecular profiles and related environmental behavior or exposure with cancer risk. Early detection studies focused primarily on testing of biomarker panels prospectively in patients at high risk for endometrial or ovarian cancer. The development of novel therapeutics continued aim at elevated biomarkers that were directly correlated with the tumor's behavior. Next generation sequencing of DNA and RNA was initiated to augment more clinically focused projects using gene and protein expression patterns. Molecular expression patterns associated with the chemo preventive affects of hormone and vitamin D regimens in both the mouse and the hen models were identified in an effort to understand the biology underlying risk reduction of endometrial and ovarian cancer respectively and to foster development of therapeutic regimens that have greater chemo preventive effect and reduced toxicity. A proof of concept vaccine trial is underway in endometrial and ovarian cancer. An intervention trial to assess the effects of stress intervention on recurrence of disease and associated changes in molecular expression is under development in patients with advanced endometrial and ovarian cancer.

***FY 2013 Plans:***

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | DATE: March 2013 |
|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>379A: *CoE-Gynecological Cancer Center of Excellence (Army)* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2012 | FY 2013 | FY 2014 |
|---|---|---|---|
| In FY13, the Gynecologic Cancer Center of Excellence is extending our previous studies of gynecologic cancer metastasis and recurrence, patient survival, drug resistance and racial disparities in cancer outcome by completing clinical assay and validation studies of the most promising biomarker panels. Molecular based prediction models with the best sensitivity, specificity, as well as positive and negative predictive value are being promoted for specific clinical indications and deployment in independent surgical and/or biopsy specimens and biofluids. Data forthcoming from molecular studies (DNA, RNA, protein) is being integrated utilizing computational biology to elucidate systems level regulatory mechanisms underlying metastasis and recurrence in endometrial cancer along with drug resistance, tumor progression, and survival in primary compared with metastatic and recurrent ovarian cancers. Approximately 600 patients with gynecologic cancer undergoing surgery for primary or recurrent disease as well as additional control patients with benign conditions undergoing a hysterectomy are being enrolled on the Tissue and Data Acquisition Network (TDAN) Protocol to collect various types of tumor and normal tissues, blood for extraction of DNA, RNA and microRNA as well as serum and urine. TDAN specimens are linked with detailed clinical, treatment, outcome and life-style questionnaire data. The prospectively collected TDAN clinical specimens and epidemiologic data are being leveraged for discovery and validation studies associated with the Early Detection and Molecular Profiling Programs in FY14. Preclinical models are being developed to optimize the chemopreventive activity of hormone and vitamin D strategies for deployment in clinical trials of endometrial cancer. Our therapeutics program is continuing to evaluate novel vaccines in ovarian and endometrial cancer, and novel designs for tailored salvage therapy trials to direct endometrial or ovarian cancer patients with specific molecular defects/ alterations to specific classes of molecular targeting agents. An intervention study is being initiated to evaluate the effects of stress intervention on recurrence of disease in ovarian cancer, and to evaluate biomarker changes. | | | |
| ***FY 2014 Plans:***<br>In FY14, the Gynecologic Cancer Center of Excellence plans to conduct retrospective longitudinal and prospective validation studies of biomarker candidates from our previous studies of gynecologic cancer metastasis and recurrence, patient survival, drug resistance and racial disparities in cancer outcome. These investigations will rely on collected specimens as well as external biospecimen collections, such as the Gynecologic Oncology Group (GOG)-249 randomized treatment trial and the Prostate, Lung, Ovarian and Colorectal (PLCO) trial. The candidates identified in our preclinical models will be evaluated in human trials as surrogates/predictors of response to progesterone/progestin and vitamin D. Hypotheses generated from systems level integration of molecular studies will be evaluated using models of ovarian and endometrial cancer. These novel hypotheses will establish the framework for the next generation of molecularly targeted therapeutics and diagnostic therapy for gynecologic cancer patient management. Novel molecular candidates will be incorporated into a newly established ensemble of safety and efficacy gynecologic cancer clinical trials aimed at directing endometrial or ovarian cancer patients with specific molecular defects/alterations to tailored molecular targeting regimens, and testing new therapeutics for treatment of newly diagnosed and recurrence/refractory (resistant, unresponsive to surgery or therapy) cancer patients. The intervention trial will remain open | | | |

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | DATE: March 2013 |
|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>379A: *CoE-Gynecological Cancer Center of Excellence (Army)* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2012 | FY 2013 | FY 2014 |
|---|---|---|---|
| to accrual to evaluate the effects of stress intervention on recurrence of disease in ovarian cancer, and to evaluate biomarker changes in serial biofluids. | | | |
| **Accomplishments/Planned Programs Subtotals** | 8.494 | 9.138 | 9.293 |

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

N/A

**Remarks**

**D. Acquisition Strategy**

N/A

**E. Performance Metrics**

Performance of the Gynecological Cancer Center of Excellence is judged on the number of active protocols, the number of articles that appear in peer-reviewed journals, and the number of contact hours in support of the training of residents and fellows in the Military Health System.

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | | DATE: March 2013 |
|---|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>381A: *CoE-Integrative Cardiac Health Care Center of Excellence (Army)* | |

| COST ($ in Millions) | All Prior Years | FY 2012 | FY 2013# | FY 2014 Base | FY 2014 OCO ## | FY 2014 Total | FY 2015 | FY 2016 | FY 2017 | FY 2018 | Cost To Complete | Total Cost |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 381A: *CoE-Integrative Cardiac Health Care Center of Excellence (Army)* | - | 3.584 | 3.857 | 3.921 | - | 3.921 | 3.993 | 4.141 | 4.210 | 4.285 | Continuing | Continuing |

# FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

## The FY 2014 OCO Request will be submitted at a later date

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

For the Cardiac Health Center of Excellence (Army), also known as the Integrative Cardiac Health Project (ICHP), the focus is the investigation of cutting edge patient-centric approaches to cardiovascular disease (CVD), risk assessment and risk reduction by incorporating biomolecular research to detect CVD at an early stage, and identifying markers of increased risk for heart attack in service members. Using a systems biology outcomes research approach, ICHP characterizes relationships between CVD, other cardio-metabolic disease states and maladaptive lifestyle behavior patterns unique to service members such as pre-diabetes, stress, overweight and sleep disorders with the aim of targeting these disorders in their pre-clinical phase and achieving ideal/optimal cardiovascular health goals outlined by the American Heart Association. ICHP's ultimate goal is to translate the evidenced-based research findings for application into clinical practice in an effort to achieve the following research aims: (1) improve Force Health by better understanding the CVD risk susceptibility of military specific populations such as Wounded Warriors through leading-edge research using novel tools and technologies, (2) investigate and create transformational models of healthcare delivery through personalized CVD prevention tracks as an adjunct to traditional care, and (3) refine individualized prevention strategies through statistical data modeling to define the most cost-effective and sustainable approaches in promoting cardiovascular health throughout the military lifecycle.

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2012 | FY 2013 | FY 2014 |
|---|---|---|---|
| ***Title:*** Cardiac Health Center of Excellence (Army) | 3.584 | 3.857 | 3.921 |
| ***Description:*** The focus is the investigation of cutting edge patient-centric approaches to cardiovascular disease (CVD), risk assessment and risk reduction by incorporating biomolecular research to detect CVD at an early stage, and identifying markers of increased risk for heart attack in service members. | | | |
| ***FY 2012 Accomplishments:***<br>In FY12, the Cardiac Health Center of Excellence (Army), also known as the Integrative Cardiac Health Project (ICHP), conducted prospective randomized investigations for comprehensive and integrative CVD risk assessment and risk reduction, prevention strategies and tools as a model of care (nutrition, weight reduction, exercise, sleep improvement and stress reduction) to promote warrior wellness and operational fitness; strategic translational research program completing scheduled longitudinal research deliverables; incorporated discovery data from genome expressions, transcriptions and proteomic patterns for early risk detection; utilized advanced data modeling of real time outcomes data to dynamically identify patterns of CVD risk that will guide optimal | | | |

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | DATE: March 2013 |
|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>381A: *CoE-Integrative Cardiac Health Care Center of Excellence (Army)* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2012 | FY 2013 | FY 2014 |
|---|---|---|---|
| evidence-based care; utilized personalized and targeted approaches for more optimal warrior wellness as a force multiplier, and continued to publish scientific results.<br><br>***FY 2013 Plans:***<br>For FY13, the Cardiac Health Center of Excellence (Army), also known as the Integrative Cardiac Health Project (ICHP), is collaborating with Physical Medicine WRNMMC to conduct a comparative cohort study to determine comprehensive CVD risk assessment in Wounded Warriors with traumatic war amputations, the first study of its kind. In another first of its kind, ICHP is performing a randomized prospective study to determine the effectiveness of the ICHP CVD risk reduction model on endothelial, diastolic, and molecular functions in patients with low 10-year CVD risk but high lifetime-risk for CVD. Many active duty members are unaware that they have low short term risk but high lifetime risk. In another study we are testing the feasibility of a novel finger stick point- of- care technology and the ICHP CVD risk reduction model to generate disease maps in pre-diabetic ICHP patients at risk for CVD. In examining a novel scientific process, ICHP is utilizing a modified serum DNA amplification process in samples from the DoD serum repository. If successful, this will be breakthrough technology to be able to obtain DNA from the DoD serum repository samples for future studies. This will be the first step to use this technique to identify young military members at risk for heart attack. ICHP is continuing development of a robust data management system. This enhanced integrative data collection is designed to capture a full picture of the individual to include physiological, behavioral, biochemical and molecular information. Our platform gathers an expansive number of data points that when leveraged can create new tools and refine processes to better define wellness, predict disease, empower patients, transform delivery to improve QOL and deliver personalized CVD prevention in the military population. ICHP's vision of lifelong cardiovascular health supports the Military Health System (MHS) Strategic Plan creating value to the MHS.<br><br>***FY 2014 Plans:***<br>In FY14, the Cardiac Health Center of Excellence (Army), also known as the Integrative Cardiac Health Project (ICHP), will continue research studies initiated in FY 12-13. Data collection from approved FY12-13 protocols will be continued as well as analyzed and synthesized. ICHP will translate and communicate best practices to the services in order to augment clinical practice. Utilizing our Knowledge to Action framework, we will incorporate findings from our studies for new hypothesis generation and development of new protocols for FY 14-18 to expand the use of point of care technology in the ICHP model, whole genome sequencing for early CVD detection, and investigate the use of serum biomarker maps for personalized CVD risk assessment in Wounded Warriors. | | | |
| **Accomplishments/Planned Programs Subtotals** | 3.584 | 3.857 | 3.921 |

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

N/A

**Remarks**

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | DATE: March 2013 |
|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>381A: *CoE-Integrative Cardiac Health Care Center of Excellence (Army)* |

**D. Acquisition Strategy**

N/A

**E. Performance Metrics**

Performance of the Cardiac Health Center of Excellence is judged on the number of active protocols, the number of articles that appear in peer reviewed journals, and the number of contact hours in support of the training of residents and fellows in the Military Health System.

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | | DATE: March 2013 |
|---|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>382A: *CoE-Pain Center of Excellence (Army)* | |

| COST ($ in Millions) | All Prior Years | FY 2012 | FY 2013# | FY 2014 Base | FY 2014 OCO ## | FY 2014 Total | FY 2015 | FY 2016 | FY 2017 | FY 2018 | Cost To Complete | Total Cost |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 382A: *CoE-Pain Center of Excellence (Army)* | - | 2.715 | 2.921 | 2.971 | - | 2.971 | 3.025 | 3.137 | 3.190 | 3.247 | Continuing | Continuing |

# FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

## The FY 2014 OCO Request will be submitted at a later date

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

The Pain Center of Excellence (Army) examines the relationship between acute and chronic pain and focuses on finding, implementing, and evaluating the most effective methods of relieving the acute pain caused by combat trauma and the effect this has throughout the continuum to rehabilitation and reintegration. The Pain Center of Excellence is an integral part of the Defense and Veterans Center for Integrative Pain Management (DVCIPM) whose mission is to become a referral center that supports world class clinical pain services, provides education on all aspects of pain management, coordinates and conducts Institutional Review Board approved clinical research and Institutional Animal Care and Use Committee approved basic laboratory and translational pain research, and serves as the advisory organization for developing enterprise-wide pain policy for the Military Health System.

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2012 | FY 2013 | FY 2014 |
|---|---|---|---|
| ***Title:*** Pain Center of Excellence (Army) | 2.715 | 2.921 | 2.971 |
| ***Description:*** The Pain Center of Excellence examines the relationship between acute and chronic pain and focuses on finding, implementing, and evaluating the most effective methods of relieving the acute pain caused by combat trauma and the effect this has throughout the continuum to rehabilitation and reintegration. | | | |
| ***FY 2012 Accomplishments:***<br>In FY12, the Pain Center of Excellence members of the Defense and Veterans Center for Integrative Pain Management (DVCIPM) remain the subject matter experts on pain in the DoD with an emphasis on improved communication across the tri-services and Veterans Health Administration. The DVCIPM provided the template for a national collaborative research foundation and provided protocol oversight and prioritization and an administrative infrastructure for service-wide pain management standardization. The protocols approved in FY11 continued data collection. The clinical research portion developed and validated best pain practices by actively tracking outcomes and populating new and existing databases. | | | |
| ***FY 2013 Plans:***<br>In FY13, the Pain Center of Excellence is reviewing data collected from approved FY11-12 protocols, and the center is writing general management and/or general practice guidelines that can be utilized in treating acute and chronic pain. Findings are being communicated to the tri-services as well as the Veterans Health Administration in an effort to standardize pain management | | | |

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | DATE: March 2013 |
|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>382A: *CoE-Pain Center of Excellence (Army)* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2012 | FY 2013 | FY 2014 |
|---|---|---|---|
| across agencies. Established protocols will continue with data collection and evaluation. Proposed protocols will obtain Institutional Review Board approval and begin data collection.<br>***FY 2014 Plans:***<br>In FY14, the Pain Center of Excellence members of the Defense and Veterans Center for Integrative Pain Management (DVCIPM) will continue to validate major lines of effort including the Defense and Veterans Pain Rating Scale (DVPRS), Pain Assessment Screening Tool and Outcomes Registry/Patient Reported Outcome Measurement Information System (PASTOR/PROMIS), and Extension for Community Healthcare Outcomes (ECHO) programs. DVCIPM will continue to explore pain management therapeutic options to develop and optimize best practice guidelines for the treatment of pain. The research program will focus on evaluation of current medications for improved pain management, clinical assimilation study of integrative medicine modalities including yoga and acupuncture, and exploration of the pathophysiology (functional change) and molecular mechanisms of pain with established and new academic partners. DVCIPM will also continue to provide subject matter expertise, coordination, and guidance to all services and Veterans Health Administration regarding pain related issues in support of the Pain Task Force. | | | |
| **Accomplishments/Planned Programs Subtotals** | 2.715 | 2.921 | 2.971 |

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

N/A

**Remarks**

**D. Acquisition Strategy**

N/A

**E. Performance Metrics**

Performance by the Pain Center of Excellence is judged on the number of active protocols, the number of articles that appear in peer reviewed journals, and the number of contact hours in support of the training of residents and fellows in the Military Health System.

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | | DATE: March 2013 |
|---|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>383A: *CoE-Prostate Cancer Center of Excellence (USUHS)* | |

| COST ($ in Millions) | All Prior Years | FY 2012 | FY 2013# | FY 2014 Base | FY 2014 OCO ## | FY 2014 Total | FY 2015 | FY 2016 | FY 2017 | FY 2018 | Cost To Complete | Total Cost |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 383A: *CoE-Prostate Cancer Center of Excellence (USUHS)* | - | 7.164 | 7.978 | 8.294 | - | 8.294 | 8.634 | 8.943 | 9.093 | 9.256 | Continuing | Continuing |

# FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

## The FY 2014 OCO Request will be submitted at a later date

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

For the Uniformed Services University of the Health Sciences (USUHS), the Prostate Cancer Center of Excellence (CoE), formerly a Congressional Special Interest program, was chartered in 1992 to conduct basic, clinical and translational research programs to combat diseases of the prostate. The program's mission is fulfilled primarily through its three principal programs- the Clinical Translational Research Center, the Basic Science Research Program and the Tri-Service Multicenter Prostate Cancer Database which encompasses its clinical research work with other participating military medical centers. These affiliated sites contribute data and biospecimens obtained from prostate cancer patients and participate in clinical trials.

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2012 | FY 2013 | FY 2014 |
|---|---|---|---|
| ***Title:*** CoE-Prostate Cancer Center of Excellence (USUHS) | 7.164 | 7.978 | 8.294 |

***Description:*** The Prostate Cancer Center of Excellence (CoE), formerly a Congressional Special Interest program, was chartered in 1992 to conduct basic, clinical and translational research programs to combat diseases of the prostate. The program's mission is fulfilled primarily through its three principal programs- the Clinical Translational Research Center, the Basic Science Research Program and the Tri-Service Multicenter Prostate Cancer Database which encompasses its clinical research work with other participating military medical centers. These affiliated sites contribute data and biospecimens obtained from prostate cancer patients and participate in clinical trials.

***FY 2012 Accomplishments:***

The Prostate Cancer COE provides state-of-the-art translational clinical research care for approximately 8,000 military beneficiaries, including 300 newly diagnosed cases of prostate cancer per year. In FY12, the Prostate Cancer CoE published 21 peer-reviewed publications and 4 invited articles. In addition, researchers at the Prostate Cancer CoE presented 6 podium presentations and 28 poster presentations at major national and international conferences. The research efforts continue to focus on ERG alterations, the most prevalent oncogenic defect for the development of a highly specific detection panel (ERG, AMACR and PCA3) for urine-based diagnosis of prostate cancer, and the therapeutic potential of targeting ERG in a large proportion of patients. Collaborations are currently in place to develop biologically relevant prognostic biomarkers and therapeutic targets for prostate cancer onset/progression. The Prostate Cancer COE is currently utilizing NextGen Sequencing technology and state-of-the-art bio-informatic software analysis via collaborators of constitutional and tumor genomic DNA to compare prostate cancer genomes of Caucasian-American and African-American patients to identify differences in molecular alterations.

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | DATE: March 2013 |
|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>383A: *CoE-Prostate Cancer Center of Excellence (USUHS)* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2012 | FY 2013 | FY 2014 |
|---|---|---|---|

The Prostate Cancer COE also utilized its training program to train 3 Urology Residents from the Walter Reed National Military Medical Center, 2 medical students from the USU, 4 postdoctoral fellows, 2 international urology fellows, and 7 undergrad and high school summer interns.

***FY 2013 Plans:***

• Evaluate new treatment strategies through innovative clinical trials to enhance the quality of life of prostate cancer patients, such as, High Frequency Focused Ultrasound, Cyber-knife, Robot-assisted Surgery and new androgen ablative mechanisms along with chemotherapeutic agents.
• Develop and enhance ERG-targeted diagnosis and therapy in prostate cancer, by translating the Prostate Cancer COE ERG monoclonal antibody into a routine diagnostic tool with a leading industrial partner for world-wide diagnosis of prostate cancer, and developing innovative strategies to inhibit ERG oncogenesis using tumor targeted nano-liposomes, small molecular inhibitors and ERG vaccine for controlling the most prevalent oncogenic activation in prostate cancer.
• Improve non-invasive approaches for detection of prostate cancer in urine or blood specimens by using ERG monoclonal antibody and complementary tools.
• Provide solution for the unmet need of prognostic biomarkers that will differentiate between indolent and aggressive disease.
• Leverage Prostate Cancer COE discoveries of Cell-specific signatures and develop new strategies of cancer genomics.
• Develop effective strategies to transform Prostate Cancer COE database and biospecimen banks to a national center for academic and industrial collaborations to accelerate translational research.
• Accelerate prostate cancer-related genome queries by acquiring high-throughput technologies such as Next-generation sequencing and Advanced bioinformatics capability.

***FY 2014 Plans:***

• Continue to conduct long-term comparisons of efficacy, morbidity, mortality and quality-of-life impact for accepted and emerging treatments for early stage prostate cancer to include robot assisted radical prostatectomy, external beam radiotherapy, brachytherapy, cryotherapy, high intensity focused ultrasound, and watchful waiting. Assess the impact of these treatments with or without neoadjuvant and adjuvant hormonal or other novel therapies
• Develop accurate prognostic models to predict organ-confined (curable) and outcome (survival) after treatment
• Conduct long-term study of the epidemiology of prostate cancer, to include the tracking of changing stage, age at diagnosis, racial makeup, long-term survival, and quality-of-life-adjusted survival
• Discover frequent and potentially causal prostate cancer gene alterations utilizing cutting edge technologies and well annotated and precisely processed bio-specimens
• Continue to evaluate cancer biology of prostate cancer relevant genes and/or proteins using established new experimental models and technologies

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | DATE: March 2013 |
|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>383A: *CoE-Prostate Cancer Center of Excellence (USUHS)* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2012 | FY 2013 | FY 2014 |
|---|---|---|---|
| • Develop new molecular strategies for improving prostate cancer diagnosis and prognosis (specifically to find replacement for PSA test)<br>• Identify molecular determinants of prostate cancer susceptibility in high-risk groups such as African-Americans<br>• Continue to develop and maintain long-term molecular specimen resources for translational investigations at CPDR and collaborations with other institutions<br>• Educate and train the next generation of basic science and translational researchers in prostate cancer<br>• Continue to enhance the Multi-national Database by building clinical models that will predict probability of prostate cancer in the diagnosis phase, optimal primary treatment in the treatment phase, and optimal recurrence treatment and outcome in the follow-up phase<br>• Integrate clinical and molecular biomarker prognostic variables for evaluating patient diagnosis, progression and treatment outcomes<br>• Create probability models via the Web that can be accessed by patients and physicians as tools for public education, patient self-testing and a physician decision support reference<br>• Develop a structured molecular oncology training program in prostate cancer for physicians and scientists | | | |
| **Accomplishments/Planned Programs Subtotals** | 7.164 | 7.978 | 8.294 |

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

N/A

**Remarks**

**D. Acquisition Strategy**

N/A

**E. Performance Metrics**

Prostate Cancer Center of Excellence: Performance is judged on the amount of extramural funding received, the number of active protocols, the number of articles that appear in peer reviewed journals, and the number of contact hours in support of the training of residents and fellows in the Military Health System.

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | | DATE: March 2013 |
|---|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>398A: *CoE-Neuroscience Center of Excellence (USUHS)* | |

| COST ($ in Millions) | All Prior Years | FY 2012 | FY 2013# | FY 2014 Base | FY 2014 OCO ## | FY 2014 Total | FY 2015 | FY 2016 | FY 2017 | FY 2018 | Cost To Complete | Total Cost |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 398A: *CoE-Neuroscience Center of Excellence (USUHS)* | - | 1.822 | 1.948 | 1.981 | - | 1.981 | 2.017 | 2.053 | 2.088 | 2.126 | Continuing | Continuing |

# FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

## The FY 2014 OCO Request will be submitted at a later date

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

For the Uniformed Services University of the Health Sciences (USUHS), the Neuroscience Center of Excellence (CoE), formerly a Congressional Special Interest program, was chartered in 2002 to conduct basic, clinical and translational research studies of militarily relevant neurological disorders affecting U.S. service members and military medical beneficiaries. The Center's mission is to improve prevention, diagnosis and treatment of neurological disorders that directly affect warfighters through a USUHS led program that collaborates broadly with military, civilian and federal medical institutions.

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2012 | FY 2013 | FY 2014 |
|---|---|---|---|
| ***Title:*** CoE-Neuroscience Center of Excellence (USUHS) | 1.822 | 1.948 | 1.981 |
| ***Description:*** The Neuroscience Center of Excellence (CoE), formerly a Congressional Special Interest program, was chartered in 2002 to conduct basic, clinical and translational research studies of militarily relevant neurological disorders affecting U.S. service members and military medical beneficiaries. The Center's mission is to improve prevention, diagnosis and treatment of neurological disorders that directly affect warfighters through a USUHS led program that collaborates broadly with military, civilian and federal medical institutions.<br><br>***FY 2012 Accomplishments:***<br>The Neuroscience Center of Excellence established an intramural competitive grant program in August 2011. The CoE issued an RFA on 15 November, 2011. The response was excellent and 24 proposals were received. The proposals were sent for external peer scientific quality review in February 2012 and the scores and rankings were received in April 2012. Since then, the proposals have been held at USUHS Office of Research before release to the Scientific Advisory Committee for their programmatic review.<br><br>***FY 2013 Plans:***<br>(1) Award grants to selected proposals. Support and coordinate implementation of research, and (2) Define priorities for a new RFP to be released as soon as FY13 funding becomes available.<br><br>***FY 2014 Plans:***<br>(1) Award grants to selected proposals. Support and coordinate implementation of research, and (2) Define priorities for a new RFP to be released as soon as FY13 funding becomes available. | | | |
| **Accomplishments/Planned Programs Subtotals** | 1.822 | 1.948 | 1.981 |

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | DATE: March 2013 |
|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>398A: *CoE-Neuroscience Center of Excellence (USUHS)* |

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

N/A

**Remarks**

**D. Acquisition Strategy**

N/A

**E. Performance Metrics**

Performance is judged on the number of active protocols, the number of articles that appear in peer reviewed journals, and the amount of extramural funding received.

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | | DATE: March 2013 |
|---|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>429A: *Hard Body Armor Testing (Army)* | |

| COST ($ in Millions) | All Prior Years | FY 2012 | FY 2013# | FY 2014 Base | FY 2014 OCO ## | FY 2014 Total | FY 2015 | FY 2016 | FY 2017 | FY 2018 | Cost To Complete | Total Cost |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 429A: *Hard Body Armor Testing (Army)* | - | 0.813 | 0.607 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | Continuing | Continuing |

# FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

## The FY 2014 OCO Request will be submitted at a later date

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

The Hard Body Armor project plans to develop a surface-mounted sensor system that will add critical dynamic data to the current clay test procedure and develops human skull fracture injury criteria for focused blunt impacts to the human head. This research develops and validates a method for assessing body armor performance against blunt trauma and will be fully compatible with the current testing method. The adoption of armor and helmet design standards that estimate injury type and severity based on biomechanics will allow designers to rationally create armor and helmets that protect each body region and allow the development of standards based on true protection outcomes.

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2012 | FY 2013 | FY 2014 |
|---|---|---|---|
| ***Title:*** Hard Body Armor | 0.813 | 0.607 | 0.000 |
| ***Description:*** Develop a surface-mounted sensor system that will add critical dynamic data to the current clay test procedure and develops human skull fracture injury criteria for focused blunt impacts to the human head.<br><br>***FY 2012 Accomplishments:***<br>The Hard Body Armor project initiated validation of system components of a surface mounted clay add-on device through field testing. The results will determine the success of the sensor system components to the surface mounted clay add-on device, a prerequisite for future live fire system field tests.<br><br>***FY 2013 Plans:***<br>The Hard Body Armor project is validating the performance of the surface mounted clay add-on device using live-fire tests of military grade armor systems. This will provide the first bio-medically valid behind-body-armor design standard allowing equipment developers to design body armor appropriate to the specific needs of each region of the body. Also, the Hard Body Armor project will determine the probability of skull fracture in relation to measured injury metrics such as head acceleration load. A body armor surface sensor working prototype will be developed. In addition, head injury prediction simulations will be conducted to associate observed skull fractures with well-defined loading/injury scenarios.<br><br>***FY 2014 Plans:***<br>No funding is programmed. | | | |
| **Accomplishments/Planned Programs Subtotals** | 0.813 | 0.607 | 0.000 |

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | DATE: March 2013 |
|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>429A: *Hard Body Armor Testing (Army)* |

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

N/A

**Remarks**

**D. Acquisition Strategy**

N/A

**E. Performance Metrics**

Principal investigators will participate in In-Progress Reviews, high-level DHP-sponsored review and analysis meetings, submit quarterly and annual status reports, and/or are subjected to Program Sponsor Representative progress review to ensure that milestones are being met and deliverables will be transitioned on schedule.

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | | DATE: March 2013 |
|---|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>431A: *Underbody Blast Testing (Army)* | |

| COST ($ in Millions) | All Prior Years | FY 2012 | FY 2013# | FY 2014 Base | FY 2014 OCO ## | FY 2014 Total | FY 2015 | FY 2016 | FY 2017 | FY 2018 | Cost To Complete | Total Cost |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 431A: *Underbody Blast Testing (Army)* | - | 14.544 | 13.142 | 11.614 | - | 11.614 | 5.353 | 2.977 | 2.077 | 0.000 | Continuing | Continuing |

# FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

## The FY 2014 OCO Request will be submitted at a later date

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

The Underbody Blast Testing medical research project will provide an understanding of the biomechanics of skeletal injuries that occur in a combat vehicle UBB event involving a landmine or IED, and to provide the biomedical basis for the development of a Warrior-representative blast test manikin and associated biomedically-validated injury criteria that can be used to characterize dynamic events and injury risks for live-fire test and evaluation (LFT&E) crew survivability assessments and vehicle development efforts to better protect Warriors from UBB threats. Current test manikins were exclusively designed for the civilian automotive industry and as such are not suitable to the combat environment. Current manikins do not represent the modern Soldier or the vertical acceleration environment associated with UBB events, consequently, current LFT&E crew survivability assessment methodologies are limited in their ability to predict the types and severity of injuries seen in these events. Due to this technology gap, military ground vehicles are being fielded without fully defined levels of injury risk and crew survivability for UBB events. There is a critical need for an enhanced blast test manikin capable of illuminating these injury mechanisms.

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2012 | FY 2013 | FY 2014 |
|---|---|---|---|
| ***Title:*** Underbody Blast Testing | 14.544 | 13.142 | 11.614 |

***Description:*** Will provide an understanding of the biomechanics of skeletal injuries that occur in a combat vehicle UBB event involving a landmine or IED, and to provide the biomedical basis for the development of a Warrior-representative blast test manikin and associated biomedically-validated injury criteria that can be used to characterize dynamic events and injury risks for live-fire test and evaluation (LFT&E) crew survivability assessments and vehicle development efforts to better protect Warriors from UBB threats.

***FY 2012 Accomplishments:***

In FY12, the Underbody Blast Testing project awarded cooperative agreements to multiple academic medical research performers to determine and characterize whole body human biofidelic (physical characteristics such as size, shape and mass) and biodynamic responses to loading conditions representative of UBB exposures. Cadaveric studies were begun to determine dynamic response, injury probability curves, and injury assessment reference values after initiation and approval of the Army cadaveric policy. The medical research strategy, integration and synchronization plans were completed to standardize research methodologies, and Jumpstart cadaveric research and Generic Hull whole body experiments were completed to provide baseline research with releasable data. UBB theater casualty injury analysis was completed to define environment, and incoming research data was evaluated by an orthopedic expert panel of clinicians to prioritize injuries and provide clinical correlation. Data from

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | DATE: March 2013 |
|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>431A: *Underbody Blast Testing (Army)* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2012 | FY 2013 | FY 2014 |
|---|---|---|---|
| research established a scientific and statistical basis for evaluating skeletal injuries to occupants during UBB events and helped finalize initial Anthropomorphic Test Device specifications.<br>***FY 2013 Plans:***<br>In FY13, the Underbody Blast Testing project plans to finalize the human response data package, including whole body kinematics, anthropometry, and ATD specifications and instrumentation for development of a prototype Gen1 ATD and accompanying injury criteria. Initial research efforts will focus on human biofidelity (physical characteristics such as size, shape, and mass) response corridors and high rate material properties for the individual body regions, with foot and ankle, lower leg, and upper extremity work completed first. There will be a sequential focus of research within a particular body region, beginning with a nominal whole body position (seated individual, primarily vertical loading for destructive testing), followed by variation in orientation and posture with more complex and/or non-vertical loadings that cause injury, all with the development of biofidelity corridors.<br>***FY 2014 Plans:***<br>The Underbody Blast Testing project will complete lower extremities biofidelity (physical characteristics such as size, shape, and mass) and human tolerance research that will enable the development and contractor evaluation phase of the Gen 1 ATD. Research data collected during FY14 will be used to begin the design of the Gen2 ATD and will focus on human injury risk curves, with work continuing on upper leg, pelvis, spine, neck and head. Medical research will add variations in boundary conditions and other initial condition, including the effect of personal protective equipment. | | | |
| **Accomplishments/Planned Programs Subtotals** | 14.544 | 13.142 | 11.614 |

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

N/A

**Remarks**

**D. Acquisition Strategy**

N/A

**E. Performance Metrics**

Principal investigators will participate in In-Progress Reviews, high-level DHP-sponsored review and analysis meetings, submit quarterly and annual status reports, and are subjected to Program Sponsor Representative progress review to ensure that milestones are being met and deliverables will be transitioned on schedule. An external peer review of the medical research strategy will be scheduled to ensure the medical research plan is on course to yield the best acceptable results.

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | | DATE: March 2013 |
|---|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>448A: *Military HIV Research Program (Army)* | |

| COST ($ in Millions) | All Prior Years | FY 2012 | FY 2013# | FY 2014 Base | FY 2014 OCO ## | FY 2014 Total | FY 2015 | FY 2016 | FY 2017 | FY 2018 | Cost To Complete | Total Cost |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 448A: *Military HIV Research Program (Army)* | - | 0.000 | 0.000 | 7.111 | - | 7.111 | 7.216 | 7.321 | 7.445 | 7.579 | Continuing | Continuing |

# FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

## The FY 2014 OCO Request will be submitted at a later date

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

This project funds research to develop candidate HIV vaccines, to assess their safety and effectiveness in human subjects, and to protect the military personnel from risks associated with HIV infection. In addition, it is designed to find ways to protect the blood supply from contamination with HIV virus. All HIV technology development is conducted in compliance with US Food and Drug Administration (FDA) regulations. Evaluations in human subjects are conducted to demonstrate safety and effectiveness of candidate vaccines, as required by FDA regulation. Studies are conducted stepwise: first, to prove safety; second, to demonstrate the desired effectiveness of the drug, vaccine, or device for the targeted disease or condition in a small study; and third, to demonstrate effectiveness in large, diverse human population trials. All results are submitted to the FDA for evaluation to ultimately obtain approval (licensure) for medical use. This project supports studies for effectiveness testing on small study groups after which they transition to the next phase of development for completion of effectiveness testing in larger populations. This program is jointly managed through an Interagency Agreement by USAMRMC and the National Institute of Allergy and Infectious Diseases (NIAID). This project contains no duplication with any effort within the Military Departments or other government organizations. The cited work is also consistent with the Assistant Secretary of Defense, Research and Engineering Science and Technology focus areas.

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2012 | FY 2013 | FY 2014 |
|---|---|---|---|
| ***Title:*** Military HIV Research Program | 0.000 | 0.000 | 7.111 |
| ***Description:*** The Military HIV Research Program aims to develop candidate HIV vaccines, to assess their safety and effectiveness in human subjects, and to protect the military personnel from risks associated with HIV infection.<br><br>***FY 2012 Accomplishments:***<br>No DHP funding programmed.<br><br>***FY 2013 Plans:***<br>No DHP funding programmed.<br><br>***FY 2014 Plans:***<br>The Military HIV Research Program will conduct safety and effectiveness studies with a combination vaccine in human volunteers at clinical trial sites world-wide and will down-select best candidates for further testing in human volunteers to study the ability of HIV vaccine candidates to provoke an immune response that can protect against HIV. | | | |
| **Accomplishments/Planned Programs Subtotals** | 0.000 | 0.000 | 7.111 |

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | DATE: March 2013 |
|---|---|---|
| **APPROPRIATION/BUDGET ACTIVITY**<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | **R-1 ITEM NOMENCLATURE**<br>PE 0603115HP: *Medical Technology Development* | **PROJECT**<br>448A: *Military HIV Research Program (Army)* |

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

N/A

**Remarks**

**D. Acquisition Strategy**

N/A

**E. Performance Metrics**

Performance of the HIV research program will be monitored and evaluated through an external peer review process, with periodic reviews by the HIV Program Steering Committee and the Military Infectious Diseases Research Program Integrating Integrated Project Team to include Health Affairs representation.

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | | DATE: March 2013 |
|---|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>830A: *Deployed Warfighter Protection (Army)* | |

| COST ($ in Millions) | All Prior Years | FY 2012 | FY 2013# | FY 2014 Base | FY 2014 OCO ## | FY 2014 Total | FY 2015 | FY 2016 | FY 2017 | FY 2018 | Cost To Complete | Total Cost |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 830A: *Deployed Warfighter Protection (Army)* | - | 5.077 | 5.472 | 5.576 | - | 5.576 | 5.691 | 5.896 | 5.997 | 6.105 | Continuing | Continuing |

# FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

## The FY 2014 OCO Request will be submitted at a later date

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

For the Armed Forces Pest Management Board (AFPMB), the Deployed Warfighter Protection project plans to develop new or improved protection for ground forces from disease-carrying insects. The focus of this program is to develop new or improved systems for controlling insects that carry disease under austere, remote, and combat conditions; understand the physiology of insecticidal activity to develop new compounds with greater specific activity and/or higher user acceptability; examine existing area repellents for efficacy and develop new spatially effective repellent systems useful in military situations; develop new methods or formulations for treating cloth to prevent vector biting; and expand the number of active ingredients and formulations of public health pest pesticides, products and application technologies available for safe, and effective applications.

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2012 | FY 2013 | FY 2014 |
|---|---|---|---|
| ***Title:*** Deployed Warfighter Protection | 5.077 | 5.472 | 5.576 |

***Description:*** The Deployed Warfighter Protection Program will develop new or improved protection for ground forces from disease-carrying insects.

***FY 2012 Accomplishments:***

The Deployed Warfighter Protection project continued to explore plans that began in FY11, such as the development of new control methods for mosquitoes, sand flies, filth flies and other insects of military importance; evaluations of equipment and pesticide efficacy trials in desert, temperate and tropical environments; improved control methods for mosquitoes and sand flies, considered the main disease-bearing insect threats to deployed forces; and the modification of insecticide application technology to better target disease carrying insects impacting military readiness. Specifically, DWFP produced 8 market-ready or near market-ready products for use by deployed military members in FY12. Several of these products are now available through the military stock system and are now in operational use. These include the Florida Fly Baiter® (FFB) filth fly killing device. The FFB and the insecticide used on the device were both produced through DWFP funding. Another killing device called the Honey Trap® received Environmental Protection Agency (EPA) registration for use against sand flies and mosquitoes. The Honey Trap® will soon be available commercially. Other significant advancements include a rodent feed-through insecticidal bait registration (Kaput®) now available to military members through the stock system and registered for use against OCONUS sand flies. This is the first known example of an EPA registered product that can be used to control pests not found in the United States. Significant advances were also made toward commercial development of another feed-through insecticide project using

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | DATE: March 2013 |
|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>830A: *Deployed Warfighter Protection (Army)* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2012 | FY 2013 | FY 2014 |
|---|---|---|---|

a different insecticide active ingredient. Numerous commercially available and experimental insecticides and sprayers were tested, with the best performers added to the military stock system. These include a new insecticide for killing adult mosquitoes and other flies and a new thermal fog sprayer that outperformed the equipment currently available to the military. A patent and licensing agreement with a commercial partner was signed for a “attract and kill” device for mosquitoes using a technique called autodissemination. Likewise, licensing agreements were signed with a commercial partner for a repellent and tick toxicant called nootkatone. Two new smart phone applications are now available to the military and civilian sector for aerial and ground insecticides (Vectorspray®).

***FY 2013 Plans:***

The Deployed Warfighter Protection project will continue 2012 efforts to add resources and develop products for the military stock system allowing deployed forces to protect themselves and control militarily important insects that bite, sting and transmit force degrading diseases. This will be accomplished through continued research, development, patent submissions, licensing and EPA registrations for new insecticides, application technologies and repellent systems. The DWFP will (1) actively pursue EPA product label changes for use against disease-carrying insects threatening deployments outside the United States; (2) continue field trials and develop reduced risk pesticides such as targeted “Sugar Baits” and other insecticides found to be effective for desert sand fly, filth and biting fly control; (3) continue cooperative work and formal agreements with industry that promotes insecticide development and EPA registration; (4) evaluate insect control materials and application technology in collaboration with military and other labs in Africa, Asia, and other global locations; (5) field next generation “lethal ovitraps” designed to attract and kill disease carrying mosquitoes; (6) continue field trials and perfect formulation of molecular (RNAi), highly specific insecticides; (7) continue field evaluations of experimental and military stock listed equipment and insecticides against CONUS and OCONUS medically important insects; (8) continue to evaluate new commercial sprayers, with best performing sprayers added to the military stock system; (9) continue assessments of how insecticide aerosols kill insects in desert, temperate and tropical environments; continue CONUS and OCONUS evaluations of spatial repellents and insecticides as barriers for sand flies and other medically important arthropods; (10) evaluate prototype of hybrid insecticide sprayers that use best attributes of existing technology; (11) continue to evaluate repellent and insecticide effectiveness for protection of military personnel wearing insecticide treated uniforms; (12) continue to validate efficacy of military issue repellents against insects that are infected with disease causing pathogens; (13) conduct field evaluations of military uniform attachments impregnated with volatile insecticide to kill and repel insects; (14) continue to identify sensory structures on mosquitoes that detect DEET and other repellent active ingredients, a basic finding that can lead to custom blends and molecular designs of new repellents; (15) continue to screen and develop plant-derived insecticides and repellents with high potential for military use; (16) continue to develop and field new insecticides and improved formulations to treat military uniforms and other military textiles used in a variety of climates; (17) develop and field new stock-listed insecticide sprayers; (18) and continue to screen chemicals for insecticidal and repellency properties.

***FY 2014 Plans:***

| Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program | | DATE: March 2013 |
|---|---|---|
| APPROPRIATION/BUDGET ACTIVITY<br>0130: *Defense Health Program*<br>BA 2: *RDT&E* | R-1 ITEM NOMENCLATURE<br>PE 0603115HP: *Medical Technology Development* | PROJECT<br>830A: *Deployed Warfighter Protection (Army)* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2012 | FY 2013 | FY 2014 |
|---|---|---|---|
| The Deployed Warfighter Protection project will continue 2012 and 2013 efforts to add resources and develop products for the military stock system allowing deployed forces to protect themselves and control militarily important insects that bite, sting and transmit force degrading diseases. This will be accomplished through continued research, development, patent submissions, licensing, and EPA registrations for new insecticides, application technologies and repellent systems. In addition to the Middle East and Africa, DWFP will prioritize research efforts that focus on militarily important arthropods (mosquitoes, sand flies, fleas, mites, ticks, and spiders), insecticides and application technologies for use in the Pacific Theater. The DWFP will (1) actively research, develop and then pursue EPA product label changes for use against disease-carrying insects threatening deployments outside the United States; (2)continue field trials and development of reduced risk pesticides; (3) continue cooperative work and formal agreements with industry that promotes development, and EPA registration; (4) evaluate insect control materials and application technology in collaborations with military and other labs in Africa, Asia and the Middle East; (5) continue field trials and perfect formulation and target sites of molecular insecticides; (6) continue field evaluations of experimental and military stock listed equipment and insecticides against medically important insects not found in the United States; (7) continue to evaluate new commercial sprayers, with best sprayers to be included in military stock system; (8)continue assessments of how insecticidal aerosols kill insects in desert, temperate and tropical environments; (9) continue overseas evaluations of spatial repellents and insecticides as barriers for sand flies and other medically important arthropods; (10) continue to develop bite resistance military uniforms; (11) conduct field evaluations of military uniform attachments impregnated with volatile insecticide to kill and repel insects; (11) continue to screen and develop plant-derived insecticides and repellents with high potential for military use; (12) continue to develop and field new insecticides and improved formulations to treat military uniforms and other military textiles used in hot, desert, temperate and tropical climates; (13) develop and field new stock-listed insecticide sprayers; (14) and continue to screen thousands of chemicals for insecticidal and repellency properties. | | | |
| **Accomplishments/Planned Programs Subtotals** | 5.077 | 5.472 | 5.576 |

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

N/A

**Remarks**

**D. Acquisition Strategy**

N/A

**E. Performance Metrics**

Performance for the Deployed Warfighter Protection Program is measured by the insecticides and other products given EPA registration and added to the military stock system, pest management techniques or technologies used by the military to control biting/disease causing insects, patents, and peer-reviewed scientific manuscripts.