Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Army											Date: May 2017	
Appropriation/Budget Activity 2040: *Research, Development, Test & Evaluation, Army I* BA 3: *Advanced Technology Development (ATD)*					R-1 Program Element (Number/Name) PE 0603002A *I Medical Advanced Technology*							
COST ($ in Millions)	**Prior Years**	**FY 2016**	**FY 2017**	**FY 2018 Base**	**FY 2018 OCO**	**FY 2018 Total**	**FY 2019**	**FY 2020**	**FY 2021**	**FY 2022**	**Cost To Complete**	**Total Cost**
Total Program Element	-	103.753	68.365	67.780	-	67.780	63.996	61.237	66.452	71.102	-	-
810: *Ind Base Id Vacc&Drug*	-	17.950	16.762	17.888	-	17.888	17.061	18.030	21.352	21.721	-	-
814: *NEUROFIBROMATOSIS*	-	15.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-
840: *Combat Injury Mgmt*	-	26.904	19.131	19.716	-	19.716	20.263	21.220	21.613	23.364	-	-
945: *BREAST CANCER STAMP PROCEEDS*	-	0.569	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-
97T: *NEUROTOXIN EXPOSURE TREATMENT*	-	16.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-
ET5: *Adv Tech Dev in Clinical & Rehabilitative Medicine*	-	0.000	11.656	9.958	-	9.958	9.151	4.893	5.057	6.766	-	-
FH4: *Force Health Protection - Adv Tech Dev*	-	1.232	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-
MM2: *MEDICAL ADVANCE TECHNOLOGY INITIATIVES (CA)*	-	8.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-
MM3: *Warfighter Medical Protection & Performance*	-	18.098	20.816	20.218	-	20.218	17.521	17.094	18.430	19.251	-	-

Note

In Fiscal Year (FY) 2017 the Clinical and Rehabilitative Medicine efforts will move from Project 840 to Project ET5. Starting in FY17 Project FH4 funding and research will move to Project MM3.

A. Mission Description and Budget Item Justification

This Program Element (PE) matures and demonstrates advanced medical technologies including drugs, vaccines, medical diagnostic devises, measures for identification and vector control, and developing medical practices and procedures to effectively protect and improve the survivability of United States Forces across the entire spectrum of military operations. Tri-Service coordination and cooperative efforts are focused in four principal medical areas: Combat Casualty Care, Military Operational Medicine, Militarily Relevant Infectious Diseases, and Clinical and Rehabilitative Medicine.

Promising medical technologies are refined and validated through extensive testing, which is closely monitored by the United States (U.S.) Food and Drug Administration (FDA) and Environmental Protection Agency (EPA), as part of their processes for licensing and/or approving new medical products. The FDA requires medical products

to undergo extensive preclinical testing in animals and/or other models to obtain preliminary effectiveness and safety information before they can be tested in human clinical trials. Clinical trials are conducted in three phases to prove the safety of a drug, vaccine, or device for the targeted disease or medical condition, starting in Phase 1 with a small number of healthy volunteers. Following Phase 1, Phase 2 clinical trials will provide expanded safety data and evaluate the effectiveness of a drug, vaccine, or medical device in a larger population of patients having the targeted disease or medical condition. Each successive phase includes larger numbers of human subjects and requires FDA cognizance prior to proceeding. Work conducted in this PE primarily focuses on late stages of technology maturation activities required to conduct Phase 1 and 2 clinical trials. Some high-risk technologies may require additional maturation with FDA guidance prior to initiating these clinical trials. Such things as proof of product stability and purity are necessary to meet FDA standards before entering later stages of testing and prior to transitioning into a formal acquisition program where large Phase 3 pivotal trials will be conducted for licensure. Activities in this PE may include completion of preclinical animal studies and Phase 1 and 2 clinical studies involving human subjects according to FDA and EPA requirements. Promising medical technologies that are not regulated by the FDA are modeled, prototyped, and tested in relevant environments.

Blast research and research into maturing field rations in this PE are fully coordinated with the United States Army Natick Soldier Research, Development, and Engineering Center. This coordination enables improved body armor design and rations for Soldiers. Additionally, the activities funded in this PE are externally peer reviewed and fully coordinated with all Services as well as other agencies through the Joint Technology Coordinating Groups of the Armed Services Biomedical Research Evaluation and Management (ASBREM) Community of Interest (COI). The ASBREM COI, formed under the authority of the Assistant Secretary of Defense for Research and Engineering, serves to facilitate coordination and prevent unnecessary duplication of effort within the Department of Defense's (DoD) biomedical research and development community, as well as its associated enabling research areas.

Project 810 matures and demonstrates FDA-regulated medical countermeasures such as drugs, vaccines, and diagnostic systems to naturally occurring infectious diseases of military importance, as identified by worldwide medical surveillance and military threat analysis. The Project also supports testing of personal protective measures such as repellents and insecticides regulated by the EPA. This Project is being coordinated with the Defense Health Program.

Project 840 validates studies on safety and effectiveness of drugs, biologics (medical products derived from living organisms), medical devices, and medical procedures and practice guidelines intended to minimize immediate and long-term effects from battlefield injuries; advanced technology development and clinical studies for treatment of ocular and visual system traumatic injury; and restoration of function and appearance by regenerating skin, muscle, nerve, vascular and bone tissues in wounded Service Members. Additionally, this Project develops and realistically tests improved occupant protection systems through medical research to characterize mechanisms of injuries sustained by occupants of ground-combat vehicles subjected to underbody blast events, determine human tolerance limits to underbody blast forces, and develop tools to predict injuries to ground-combat vehicle occupants exposed to underbody blast forces. Starting in FY17 the funding for the Clinical and Rehabilitative Medicine Research Program moves from Project 840 to Project ET5.

Project ET5 which is a restructure of efforts funded elsewhere in this Program Element, starts in FY17 and the funding for the Clinical and Rehabilitative Medicine Research Program moves from Project 840 to Project ET5. Project ET5 conducts validation studies on safety and effectiveness of drugs, biologics, medical devices, procedures, and rehabilitative strategies intended to minimize long-term effects from battlefield injuries. This Project supports advancing technology supporting clinical and rehabilitative solutions to restore function of ocular and visual system post injury; and advancing regenerative techniques to restore the function and appearance of damaged tissues by regenerating skin, muscle, nerve, vascular and bone tissues in wounded Service Members.

Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Army	Date: May 2017
Appropriation/Budget Activity 2040: *Research, Development, Test & Evaluation, Army I* BA 3: *Advanced Technology Development (ATD)*	**R-1 Program Element (Number/Name)** PE 0603002A *I Medical Advanced Technology*

Project FH4 matures, validates, and supports enhanced Force Health Protection of Soldiers against threats in military operations and training. Health-monitoring tools are matured to rapidly identify deployment stressors that affect the health of Joint Forces. These databases and systems enhance the DoDs ability to monitor and protect against adverse changes in health, especially mental health effects caused by changes in brain function. Force Health Protection work is conducted in close coordination with the Department of Veterans Affairs. The program is maturing the development of global health monitoring (e.g., development of neuropsychological evaluation methodologies), validating clinical signs and symptoms correlating to medical records, diagnosed diseases, and mortality rates. The key databases supporting this program are the Millennium Cohort Study and the Total Army Injury and Health Outcomes Database. These databases allow for the examination of interactions of psychological stress and other deployment and occupational stressors that affect Warfighter health behaviors. Starting in FY17 the FH4 funding and research will be merged into Project MM3.

Project MM3 supports the Medical and Survivability technology areas with laboratory validation studies and field demonstrations of biomedical products designed to counteract myriad environmental and physiological stressors, as well as materiel hazards encountered in training and operational environments to protect, sustain, and enhance Soldier performance. The key efforts are to demonstrate and transition technologies, as well as validate tools associated with Soldier survivability, injury assessment and prediction, assessments for post-concussive syndrome, and enhancing performance during continuous operations. The three main thrust areas are: 1) Physiological Health and Environmental Protection; 2) Injury Prevention and Reduction; and 3) Psychological Health and Resilience. This Project contains no duplication with any effort within the Military Departments and includes direct participation by other Services. Starting in FY17 the FH4 funding and research will be merged into Project MM3.

Work funded in this PE is fully coordinated with efforts undertaken in PE 0602787A and the Defense Health Program.

The cited work is consistent with the Assistant Secretary of Defense, Research and Engineering Science and Technology, focus areas and the Army Modernization Strategy.

Work in this PE is performed by Walter Reed Army Institute of Research (WRAIR), Silver Spring, MD; United States Army Medical Research Institute of Infectious Diseases (USAMRIID) and the Armed Forces Institute of Regenerative Medicine (AFIRM), Ft Detrick, MD; United States Army Research Institute of Environmental Medicine (USARIEM), Natick, MA; United States Army Institute of Surgical Research, Joint Base San Antonio, TX; United States Army Aeromedical Research Laboratory (USAARL), Ft Rucker, AL; the Naval Medical Research Center (NMRC), Silver Spring, MD; United States Army Dental Trauma Research Detachment (USADTRD), Joint Base San Antonio, TX.

Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Army	Date: May 2017
Appropriation/Budget Activity 2040: *Research, Development, Test & Evaluation, Army I* BA 3: *Advanced Technology Development (ATD)*	**R-1 Program Element (Number/Name)** PE 0603002A *I Medical Advanced Technology*

B. Program Change Summary ($ in Millions)	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Previous President's Budget	108.584	68.365	70.847	-	70.847
Current President's Budget	103.753	68.365	67.780	-	67.780
Total Adjustments	-4.831	0.000	-3.067	-	-3.067
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-4.831	-			
• Adjustments to Budget Years	0.000	0.000	-3.179	-	-3.179
• Civ Pay Adjustments	0.000	0.000	0.112	-	0.112

Congressional Add Details ($ in Millions, and Includes General Reductions)	FY 2016	FY 2017
Project: 814: *NEUROFIBROMATOSIS*		
Congressional Add: *Neurofibromatosis Research Program*	15.000	-
Congressional Add Subtotals for Project: 814	15.000	-
Project: 97T: *NEUROTOXIN EXPOSURE TREATMENT*		
Congressional Add: *Peer-Reviewed Neurotoxin Exposure Treatment Parkinsons Research Program*	16.000	-
Congressional Add Subtotals for Project: 97T	16.000	-
Project: MM2: *MEDICAL ADVANCE TECHNOLOGY INITIATIVES (CA)*		
Congressional Add: *Military Burn Trauma Research Program*	8.000	-
Congressional Add Subtotals for Project: MM2	8.000	-
Congressional Add Totals for all Projects	39.000	-

Exhibit R-2A, RDT&E Project Justification: FY 2018 Army			Date: May 2017
Appropriation/Budget Activity 2040 / 3	R-1 Program Element (Number/Name) PE 0603002A / *Medical Advanced Technology*	Project (Number/Name) 810 / *Ind Base Id Vacc&Drug*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
810: *Ind Base Id Vacc&Drug*	-	17.950	16.762	17.888	-	17.888	17.061	18.030	21.352	21.721	-	-

Note

In Fiscal Year (FY) 2017 the Drugs to Prevent/Treat Parasitic Diseases and Vaccines for Prevention of Malaria research areas are merged into Advanced Technology on drugs and vaccines against parasitic diseases.

A. Mission Description and Budget Item Justification

This Project maturates and demonstrates United States (U.S.) Food and Drug Administration (FDA)-regulated medical countermeasures such as drugs, vaccines, and diagnostic (identification of the nature and cause of a particular disease) systems to naturally occurring infectious diseases that are threats to deployed United States military forces. The focus of the Project is on prevention, diagnosis, and treatment of diseases that can adversely impact military mobilization, deployment, and operational effectiveness. Prior to licensure of a new drug or vaccine to treat or prevent disease, the FDA requires testing in human subjects. Studies are conducted stepwise: first to prove the product is safe in humans, second to demonstrate the desired effectiveness and optimal dosage (amount to be administered) in a small study, and third to demonstrate effectiveness in large, diverse human populations. All test results are submitted to the FDA for evaluation to ultimately obtain approval (licensure) for medical use. This Project supports the studies for safety and effectiveness testing on small study groups after which they transition to the next phase of development for completion of expanded safety and initial studies for effectiveness in larger populations. If success is achieved for a product in this Project, the effort will transition into Advanced Development. The Project also supports testing of personal protective measures that can reduce disease transmission from arthropods to include products such as repellents and insecticides, which are regulated by the Environmental Protection Agency (EPA).
Research conducted in this Project focuses on the following four areas:

(1) Prevention/Treatment of Parasitic (organism living in or on another organism) Diseases
(2) Bacterial Disease Threats (diseases caused by bacteria)
(3) Viral Disease Threats (diseases caused by viruses)
(4) Diagnostic Systems and Vector Identification and Control

Research is conducted in compliance with FDA regulations for medical products for human use and EPA regulations for insect-control products that impact humans or the environment (e.g., repellents and insecticides).

Work is managed by the United States Army Medical Research and Materiel Command (USAMRMC) in coordination with the Naval Medical Research Center (NMRC). The Army is responsible for programming and funding all Department of Defense (DoD) naturally occurring infectious disease research requirements, thereby precluding duplication of effort within the Military Departments.

Promising medical countermeasures identified in this Project are further matured under Program Element 0603807A, Project 808.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Army		Date: May 2017
Appropriation/Budget Activity 2040 / 3	**R-1 Program Element (Number/Name)** PE 0603002A / *Medical Advanced Technology*	**Project (Number/Name)** 810 / *Ind Base Id Vacc&Drug*

The cited work is consistent with the Assistant Secretary of Defense, Research and Engineering Science and Technology, focus areas and the Army Modernization Strategy.

Work in this Project is performed by the Walter Reed Army Institute of Research (WRAIR), Silver Spring, MD, and its overseas laboratories; the U.S. Army Medical Research Institute of Infectious Disease (USAMRIID), Fort Detrick, MD; and the NMRC, Silver Spring, MD, and its overseas laboratories.

Efforts in this Project support the Soldier portfolio and the principal area of Military Relevant Infectious Diseases.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Drugs to Prevent/Treat Parasitic Diseases	1.958	-	-
Description: This effort selects promising anti-parasitic drug candidates for treating malaria and leishmaniasis (a disease transmitted by sand flies) for testing in humans, prepares data packages required for FDA approval of testing in humans, and conducts that testing. Studies have shown that the malaria parasite can become resistant to existing drugs, which makes it necessary to continually research new and more effective treatments. In FY17 this research area and the Vaccines for Prevention of Malaria research area are merged into one task area titled Advanced Technology Research on drugs and vaccines against parasitic diseases.			
FY 2016 Accomplishments: The down-selected compounds from Triazine group showing positive results in small animal testing in FY15 were used in clinical testing for safety and effectiveness in human volunteers. Conducted clinical testing to assess metabolism (break-down within human body) of 8-aminoquinoline class drugs (i.e. primaquine) to improve drug safety and effectiveness for treatment and prevention of relapsing malarias (persons getting sick second time after drug treatment). Transitioned best therapeutic (treatment or drug promoting disease healing) and preventive drug candidates to advanced development.			
Title: Vaccines for Prevention of Malaria	4.734	-	-
Description: This effort selects candidate vaccines for various types of malaria, including the severe form of malaria (Plasmodium falciparum) and the less severe but relapsing form (Plasmodium vivax), prepares technical data packages required for FDA approval of testing in humans and conducts testing of promising malaria vaccine candidates in humans. A malaria vaccine would minimize the progression and impact of drug resistance and poor Warfighter compliance with taking preventive anti-malarial drugs. In FY17 this research area and the Drugs to Prevent/Treat Parasitic Diseases research area are merged into one task area titled Advanced Technology Research on drugs and vaccines against parasitic diseases.			
FY 2016 Accomplishments:			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Army		Date: May 2017
Appropriation/Budget Activity 2040 / 3	**R-1 Program Element (Number/Name)** PE 0603002A / *Medical Advanced Technology*	**Project (Number/Name)** 810 / *Ind Base Id Vacc&Drug*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Continued conducting human safety and effectiveness clinical trials of new formulations of vaccine candidates including weakened (so they do not cause disease) malaria sporozoites (infective stage of the parasite) in human volunteers to assess their safety and effectiveness. Down-selected the best vaccine candidate for transition to advanced development.			
Title: Advanced Technology Research on drugs and vaccines against parasitic diseases ***Description:*** This effort selects promising anti-parasitic drug candidates for treating malaria and leishmaniasis for testing in humans, prepares data packages required for FDA approval of testing in humans. Studies have shown that the malaria parasite can become resistant to existing drugs, which makes it necessary to continually develop new and more effective and safe treatments. This effort selects candidate vaccines for various types of malaria, including the severe form of malaria (Plasmodium falciparum) and the less severe but relapsing form (Plasmodium vivax), prepares technical data packages required for FDA approval of testing in humans and conducts testing of promising malaria vaccine candidates in humans. A malaria vaccine would minimize the progression and impact of drug resistance and poor Warfighter compliance with taking preventive anti-malarial drugs. In FY17 the Vaccines for Prevention of Malaria research area and the Drugs to Prevent/Treat Parasitic Diseases research area are merged into this task area titled Advanced Technology Research on drugs and vaccines against parasitic diseases. ***FY 2017 Plans:*** Will down-select a lead compound from Triazine group which will be used in clinical testing for safety and effectiveness (protection against controlled human malaria infection) in human volunteers. Will conduct clinical testing of eight-aminoquinoline class drugs (i.e. primaquine) to assess the break-down within human body in order to improve drug safety and effectiveness for treatment and prevention of relapsing malarias (persons getting sick second time after drug treatment). Will conduct trials in human volunteers with recombinant DNA and viral vector based vaccine candidates to assess their safety and effectiveness. Will test new particle based platform (self-assembling protein nanoparticle based vaccine) in humans to improve performance of selected vaccine candidates. Will down-select the best vaccine candidate for transition to advanced development. ***FY 2018 Plans:*** Will submit initial human testing data for FDA review and down-select lead Triazine compound for further human testing. Will assess improved strategy for safe and more effective use of primiquine-like drugs for radical cure in humans. Will continue to conduct trials in human volunteers using multiple technologies to evaluate efficacy of selected vaccine candidates in a controlled human malaria infection model.	-	6.591	6.916
Title: Bacterial Disease Threats ***Description:*** This effort selects promising candidate vaccines against each of the three main bacterial causes of diarrheas (E. coli, Campylobacter, and Shigella; that pose significant threat during initial deployments) for testing in human subjects. Data packages are prepared, as required for FDA approval, and testing is conducted in human subjects.	4.518	3.880	4.291

Exhibit R-2A, RDT&E Project Justification: FY 2018 Army		Date: May 2017
Appropriation/Budget Activity 2040 / 3	**R-1 Program Element (Number/Name)** PE 0603002A / *Medical Advanced Technology*	**Project (Number/Name)** 810 / *Ind Base Id Vacc&Drug*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
FY 2016 Accomplishments: Prepared data packages to present to the FDA for approval for human testing of vaccine candidates for bacterial diarrheal agents. Conducted extended safety and effectiveness studies by using different escalating doses of down selected vaccine candidates against each of the three diarrheal agents (Shigella, Enterotoxigenic E. coli (ETEC) and Campylobacter) in human volunteers. Transitioned the best Shigella, ETEC & Campylobacter vaccine candidates, respectively, to Advanced Development. ***FY 2017 Plans:*** Will complete clinical trials with monovalent (one type) additional vaccine candidates identified in FY16 to present to the FDA for approval for human testing of vaccine candidates for bacterial diarrheal agents. Will conduct extended safety/efficacy/dosing study in humans by using different escalating doses of candidate vaccines against Shigella, and ETEC. This will also allow understanding protection mechanisms of these vaccine candidates. Will transition the new Shigella, and ETEC vaccine candidates to Advanced Development. ***FY 2018 Plans:*** Will conduct expanded (FDA) safety/initial efficacy study in humans for Shigella and ETEC vaccine candidates. Will perform analyses of samples obtained from human safety studies and make decisions regarding advancement of vaccine candidates for further testing at field sites. Will conduct initial (FDA) safety study in humans for a Campylobacter vaccine candidate. Will perform analyses of samples obtained from safety study of the Campylobacter vaccine candidate and make a decision regarding advancement of this candidate in efficacy testing studies.			
Title: Viral Disease Threats	5.116	5.035	5.000
Description: This effort progresses the most promising vaccine candidates against dengue fever (a severe debilitating disease caused by a virus and transmitted by a mosquito)and hantavirus (severe viral infection that causes internal bleeding and is contracted from close contact with rodents), as well as conducts FDA-required nonclinical safety and protection testing (laboratory- based) in animals, prepares FDA investigational new drug technical data packages, and conducts clinical testing of candidate vaccines in humans.			
FY 2016 Accomplishments: Conducted assessments of vaccine effectiveness and safety among human populations immunized with experimental dengue vaccines. Continued development and testing of the experimental dengue human challenge model initiated in FY15. Continued clinical trials with candidate deoxyribonucleic acid (DNA) vaccine against hantaviruses and continue to look for a commercial partner and a country where hantaviruses infections regularly occur, to conduct large scale clinical trials (FDA required). Coordinated with the FDA to establish specific guidelines for the licensure of a hantavirus DNA vaccine.			
FY 2017 Plans:			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Army		Date: May 2017
Appropriation/Budget Activity 2040 / 3	**R-1 Program Element (Number/Name)** PE 0603002A / *Medical Advanced Technology*	**Project (Number/Name)** 810 / *Ind Base Id Vacc&Drug*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Will assess safety and initial immunogenicity (ability to provoke an immune response) of vaccine candidates measured from sera and immune cells obtained from human volunteers enrolled in dengue vaccine trial conducted with commercial partner. Will assess safety of controlled human dengue infection with newly developed Dengue attenuated viruses that will be used in future clinical trials in lieu of natural infection caused by mosquito bite to assess effectiveness of candidate dengue vaccines. Will assess if antibody responses will be acceptable over a traditional expanded safety, efficacy, and dosing studies in humans. There is currently no animal disease model for Hantavirus causing Hemorrhagic Fever with Renal Syndrome. Could prove difficult to conduct a traditional safety/efficacy/dosing study in humans for vaccine assessment due to the marginally low incidence of disease, we will pursue a vaccine efficacy evaluation strategy based on establishing surrogate markers of protection, i.e. antibodies that neutralize the virus(es) against the disease. ***FY 2018 Plans:*** Will assess safety and immunogenicity (ability to provoke an immune response) of vaccine candidates measured from sera (body fluids) and immune cells obtained from human volunteers enrolled in new dengue vaccine trial conducted with commercial partner. Will continue to evaluate safety of controlled human dengue infection model with newly developed Dengue viruses. Will validate effectiveness of candidate dengue vaccines using challenge model (mimics dengue in a controlled setting by infecting human volunteers with a weakened live dengue virus and measuring outcome. Will conduct human trials to evaluate the biological activity of the DNA-based vaccine to prevent Hemorrhagic Fever with Renal Syndrome (HFRS).			
Title: Diagnostics and Disease Transmission Control ***Description:*** This effort conducts human subject testing of FDA-regulated field medical diagnostic devices and EPA-approved measures to control arthropods (i.e. insects, ticks & mites)-borne pathogens (infectious agents) that cause diseases such as Q fever, Sand fly fever, and Japanese encephalitis. ***FY 2016 Accomplishments:*** Supported projects to research and develop rapid human diagnostic devices (RHDDs) for priority diseases and pathogens (infectious agents) that are usable at or near the point of need. Developed military relevant assays (i.e. panels differentiating diseases that have similar symptoms) to be transitioned for the next-generation diagnostic system (NGDS) platform. Continued to test new vector control technologies in the field. ***FY 2017 Plans:*** Will conduct laboratory and field evaluations with commercial partners and outside of the continental United States (OCONUS) laboratories to evaluate RHDDs and Arthropods Vector Rapid Detection Device (AVRDDs) for infectious agents of military importance. The aim is to conduct initial validation studies required to ensure that the commercial assay meets military requirements and has the potential to obtain the requisite regulatory clearances from the FDA to facilitate military use. Will test	1.624	1.256	1.681

Exhibit R-2A, RDT&E Project Justification: FY 2018 Army		Date: May 2017
Appropriation/Budget Activity 2040 / 3	**R-1 Program Element (Number/Name)** PE 0603002A / *Medical Advanced Technology*	**Project (Number/Name)** 810 / *Ind Base Id Vacc&Drug*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
new generation spatial repellant(s) in the field for efficacy against insect and other arthropod vectors. Will test bite-protection/ resistance capability of repellant treated fabrics. ***FY 2018 Plans:*** Will advance the evaluation of new generation spatial repellant(s) in the field for efficacy against insect and other arthropod vectors. Will continue to perform laboratory and field evaluations with commercial partners and OCONUS laboratories to evaluate rapid diagnostic assays for infectious agents applicable to military interests.			
Accomplishments/Planned Programs Subtotals	17.950	16.762	17.888

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: FY 2018 Army			Date: May 2017
Appropriation/Budget Activity 2040 / 3	R-1 Program Element (Number/Name) PE 0603002A / *Medical Advanced Technology*	Project (Number/Name) 814 / *NEUROFIBROMATOSIS*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
814: *NEUROFIBROMATOSIS*	-	15.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-

A. Mission Description and Budget Item Justification

Congressional Interest Item funding for Neurofibromatosis research.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017
Congressional Add: Neurofibromatosis Research Program	15.000	-
FY 2016 Accomplishments: Neurofibromatosis Research Program		
Congressional Adds Subtotals	15.000	-

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: FY 2018 Army			Date: May 2017
Appropriation/Budget Activity 2040 / 3	R-1 Program Element (Number/Name) PE 0603002A / *Medical Advanced Technology*	Project (Number/Name) 840 / *Combat Injury Mgmt*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
840: *Combat Injury Mgmt*	-	26.904	19.131	19.716	-	19.716	20.263	21.220	21.613	23.364	-	-

Note

In Fiscal Year (FY) 2017 the Clinical and Rehabilitative Medicine funding will move to Project ET5.

A. Mission Description and Budget Item Justification

This Project matures, demonstrates, and validates promising medical technologies and new clinical practices for control of severe bleeding, treatment for traumatic brain injury (TBI), resuscitation and stabilization of trauma patients, acute treatment of extremity (arms and legs) and facial injuries, treatment of severe burn wounds, treatment of single and multiple organ failures due to trauma, and predictive indicators and decision aids for life support systems. Post-evacuation medical research focuses on continued care and rehabilitative medicine for extremity, facial/maxillary (jaw bone), and ocular (eye) trauma and leveraging recent innovations in regenerative medicine and tissue engineering techniques.

Research conducted in this project focuses on the following five areas:

(1) Damage Control Resuscitation
(2) Combat Trauma Therapies
(3) Traumatic Brain Injury
(4) Combat Critical Care Engineering
(5) Clinical and Rehabilitative Medicine (moves to Project ET5 in FY17)

All research is conducted in compliance with Food and Drug Administration (FDA) requirements for licensure of medical products for human use.

Promising efforts identified through applied research conducted under Program Element (PE) 0602787A, Project 874, are further matured under this Project. Promising results identified under this Project (840) are further matured under PE 0603807A, Project 836.

The cited work is consistent with the Assistant Secretary of Defense, Research and Engineering Science and Technology, focus areas and the Army Modernization Strategy.

Work in this Project is performed by the United States (U.S.) Army Institute of Surgical Research (USAISR), Joint Base San Antonio, TX; the Walter Reed Army Institute of Research (WRAIR), Silver Spring, MD; and the Armed Forces Institute of Regenerative Medicine (AFIRM), at Multiple Institutions across the U.S.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Damage Control Resuscitation	7.200	6.183	6.035

Exhibit R-2A, RDT&E Project Justification: FY 2018 Army		Date: May 2017
Appropriation/Budget Activity 2040 / 3	**R-1 Program Element (Number/Name)** PE 0603002A / *Medical Advanced Technology*	**Project (Number/Name)** 840 / *Combat Injury Mgmt*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Description: This effort supports work required to validate safety and effectiveness of drugs and medical procedures to control bleeding, maintain metabolism (the chemical processes that are required to maintain life) and minimize harmful inflammation after major trauma. Efforts focus on stopping bleeding, preserving tissue function and preventing or minimizing secondary organ failure (including brain and spinal cord injury). ***FY 2016 Accomplishments:*** Continued research from FY15 to evaluate hemostatic drugs, biologics, devices and techniques in relevant traumatic bleeding shock models. Extended FY15 work, evaluated promising hemostatic devices designed to stop bleeding in body locations where tourniquets cannot be used; evaluations were done in manikins and normal human volunteers. Evaluated preclinical safety of emerging platelet storage technologies with respect to preserving platelet hemostatic function and preventing an adverse inflammation response. ***FY 2017 Plans:*** Will evaluate existing drugs, devices, and techniques to stop severe bleeding in relevant hemorrhagic shock models and in humans. Will validate small volume resuscitative therapies, i.e., medicinal products that protect blood-deprived tissues from further damage and restore normal cell function. Smaller volume resuscitative products permit the medic to carry more products in aid bag, which increases availability for use at the point of injury in far forward areas. ***FY 2018 Plans:*** Will perform preclinical studies to evaluate stem cell therapies in an animal model of severe traumatic bleeding. Will evaluate currently available and new products for control of compressible bleeding under prolonged field care scenarios, i.e., when medical evacuation is delayed and/or prolonged. Will perform animal studies to determine impact of prolonged hypotensive (low blood pressure) resuscitation, due to delayed evacuation, on subsequent survival once patient receives definitive surgical care and full resuscitation. Will evaluate different types of mechanical interventions (e.g., compression, wound packing, use of tourniquets) to determine optimal practices for control of bleeding from junctional wounds. Will continue to evaluate small volume resuscitative therapies with blood products and hemostatic drugs (drugs that stop or slow down the flow of blood) to identify combinations that optimally mitigate the effects of inflammation and prolonged ischemia (inadequate or absent blood supply) in critical tissues. Will evaluate methods to refrigerate whole blood that do not impair platelet function.			
Title: Combat Trauma Therapies	3.508	5.467	6.343
Description: This effort focuses on work required to validate safety and effectiveness of drugs, biologics, and medical procedures intended to minimize immediate and long-term effects from battlefield injuries. ***FY 2016 Accomplishments:***			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Army		Date: May 2017
Appropriation/Budget Activity 2040 / 3	**R-1 Program Element (Number/Name)** PE 0603002A / *Medical Advanced Technology*	**Project (Number/Name)** 840 / *Combat Injury Mgmt*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
As follow on to research from FY15, evaluated therapies to reduce fibrosis (development of excessive connective tissue after injury) during recovery from large volume muscle loss injury and improve muscle functionality. Performed small clinical studies to characterize effects of traumatic and burn injuries on vital organ preservation, scarring, and need for pain-relieving drugs. Fielded an information product on a predictive model to estimate dental casualties for Soldiers entering a theater of operations. ***FY 2017 Plans:*** Will pre-clinically validate combined-agent (a bacteria-killing protein in combination with a chemical that disperses bacterial colonies) antibacterial wound treatments in a large animal contaminated facial, mouth wound model. As follow on to the FY16 work, will evaluate therapies that reduce excessive connective tissue formation following traumatic muscle injury to determine their effect on remaining muscle and surgical repair. Will perform clinical studies to determine factors that impede wound healing. Will perform clinical studies to determine the burden of excessive scarring from burn injuries. ***FY 2018 Plans:*** Follow on work to evaluate therapies that reduce excessive scar tissue formation following traumatic muscle injury will move under Clinical and Rehabilitative Medicine. Will perform studies to determine impact of prolonged tourniquet use on antibiotic concentrations at wound site. Will perform retrospective analyses to identify clinical determinants of long-term disability in casualties with musculoskeletal injuries. Will perform animal studies to determine optimal concentration of dilute hypochlorite for initial wash-out of dismounted complex battlefield injuries. Will perform preclinical studies to validate combined-agent (a bacteria-killing protein in combination with a chemical that disperses bacterial colonies) antibacterial wound treatments in a large animal contaminated facial, mouth wound model.			
Title: Traumatic Brain Injury (TBI) ***Description:*** This effort supports work required to validate safety and effectiveness of drugs, biologics, and medical procedures intended to minimize immediate and long-term effects from TBI. ***FY 2016 Accomplishments:*** Examined promising therapies to protect brain cells following TBI using relevant animal models of penetrating and concussive TBI. Performed studies to establish drug protocols targeting the sub-acute (within the first few days following TBI) and chronic TBI recovery phases. Continued research from FY15 to evaluate effectiveness (therapeutic effect or benefit) of different drug combinations to protect brain cells following TBI. ***FY 2017 Plans:*** Will begin pre-clinical and early clinical studies of post-TBI hyperthermia (TBI-induced fever). Will begin pre-clinical and early clinical studies of potential neuro-regenerative mechanisms (mechanisms to restore damaged brain tissue). Will validate	4.062	4.192	4.085

Exhibit R-2A, RDT&E Project Justification: FY 2018 Army		Date: May 2017
Appropriation/Budget Activity 2040 / 3	**R-1 Program Element (Number/Name)** PE 0603002A / *Medical Advanced Technology*	**Project (Number/Name)** 840 / *Combat Injury Mgmt*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
neuroprotection therapies (therapies to protect brain tissue from further damage following a TBI event) using validated small animal model of polytrauma (multiple traumatic injuries). ***FY 2018 Plans:*** Will complete studies to mitigate post-TBI hyperthermia (TBI-induced fever) and transition knowledge to clinical practice guidelines. Will continue to further evaluate two neuroprotective drugs (therapies to protect brain tissue from further damage following a TBI event) with demonstrated synergistic effects in animal models of TBI. Will use a small animal model of severe TBI to evaluate the potential beneficial effects of resuscitative endovascular balloon occlusion of the aorta (a surgical technology used to control non-compressible hemorrhage in the abdomen) on TBI outcomes.			
Title: Combat Critical Care Engineering ***Description:*** This effort supports development of diagnostic and therapeutic medical devices, algorithms, software, and data-processing systems for resuscitation, stabilization and life support, and development of improved critical care nursing practices to improve care of severely injured or ill casualties during transport and in theater hospitals and development and evaluation of technologies to treat vital organ failure caused by traumatic injury. ***FY 2016 Accomplishments:*** Evaluated militarily relevant pre-hospital care technologies used in existing civilian trauma system, including improved patient monitors with decision support algorithms to predict shock, life-saving intervention technologies and evaluation of telehealth direction of remote surgical procedure. Concluded work on ventilation strategies and transition to advanced development. Started clinical studies to support development of combat nursing clinical practice guidelines for en-route care and for management of sepsis (whole-body inflammation caused by an infection) in the burn intensive care unit. Performed translational studies of promising technologies to treat single and multiple organ failure due to trauma. ***FY 2017 Plans:*** Will use an animal model of survivable lung injury to test effectiveness of various therapeutic approaches. Will validate the FDA-approved Resuscitation Burn Decision Support System for other indications. Will continue work from FY16 to develop clinical practice guidelines for en-route nursing care and for identification and management of sepsis. Will perform clinical studies to determine best practice to prevent pressure ulcer development during evacuation. ***FY 2018 Plans:*** Will evaluate inhalation delivery of stem cells to treat lung injury in animal model. Will continue to clinically evaluate means to prevent pressure ulcer development during evacuation. Will transition knowledge from enroute nursing care and sepsis (the condition or syndrome caused by the presence of microorganisms or their toxins in the tissue or the bloodstream) management to	3.692	3.289	3.253

Exhibit R-2A, RDT&E Project Justification: FY 2018 Army		Date: May 2017
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B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
clinical practice guidelines. Will perform animal studies to determine effects of endovascular balloon occlusion of the aorta (used for control of intra-abdominal bleeding) on organ function to ensure use is optimized to prevent organ failure and death.			
Title: Clinical and Rehabilitative Medicine ***Description:*** This effort supports clinical studies to advance treatment and restoration strategies of traumatically-injured tissues, to include skin, nerve, bone and ocular tissue to ultimately restore function and appearance. Areas of interest for regenerative medicine include healing without scarring, repair of compartment syndrome (muscle and nerve damage following reduced blood flow caused by swelling), replacement skin, and facial reconstruction. In FY17 the Clinical and Rehabilitative Medicine funding will move to project ET5. ***FY 2016 Accomplishments:*** Executed preclinical studies of drug delivery, diagnostic, tissue repair, and/or treatment strategies for traumatic eye injury and assessed the preclinical safety and efficacy of promising strategies to facilitate clinical translation. Further advanced novel drug delivery, diagnostic, reconstructive, and regenerative strategies including novel biological materials and cell-based therapies (i.e. stem cells) toward clinical translation; utilized and refined the combination of cell-based therapies and tissue scaffolds to restore soft and bone tissue form and function; enhanced promising approaches from FY2015 by advancing to preclinical safety and efficacy studies to enable clinical evaluation of candidate strategies for burn, scarless wound healing, bone and soft tissue repair, and strategies to repair the tissues of the extremities, craniomaxillofacial, genital and abdominal regions. Evaluated improved monitoring technologies for tissue rejection during hand and face transplant procedures for advancement into clinical trials.	7.886	-	-
Title: Administrative Activities for Prior Year Clinical Trials ***Description:*** Contract law requires the government to fulfill its responsibilities for the life of the Congressional Special Interest (CSI) award as stated in the terms and conditions. Each award may have an execution and award management tail of up to 5 years post-award, which usually occurs 18 months after the start of the fiscal year. This effort concludes at the end of FY16. ***FY 2016 Accomplishments:*** Continued funding for scientific expertise, legal, contracting, research protections, regulatory affairs, and resource support personnel to manage active projects.	0.556	-	-
Accomplishments/Planned Programs Subtotals	26.904	19.131	19.716

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

Exhibit R-2A, RDT&E Project Justification: FY 2018 Army		Date: May 2017
Appropriation/Budget Activity 2040 / 3	**R-1 Program Element (Number/Name)** PE 0603002A / *Medical Advanced Technology*	**Project (Number/Name)** 840 / *Combat Injury Mgmt*

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: FY 2018 Army			Date: May 2017
Appropriation/Budget Activity 2040 / 3	R-1 Program Element (Number/Name) PE 0603002A / *Medical Advanced Technology*	Project (Number/Name) 945 / *BREAST CANCER STAMP PROCEEDS*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
945: *BREAST CANCER STAMP PROCEEDS*	-	0.569	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-

A. Mission Description and Budget Item Justification

This project receives funds as proceeds from the sale of Breast Cancer Stamps.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Breast Cancer Stamp Proceeds	0.569	-	-
Description: This is a Congressional Interest Item.			
FY 2016 Accomplishments: blank			
Accomplishments/Planned Programs Subtotals	0.569	-	-

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: FY 2018 Army			Date: May 2017
Appropriation/Budget Activity 2040 / 3	R-1 Program Element (Number/Name) PE 0603002A / *Medical Advanced Technology*	Project (Number/Name) 97T / *NEUROTOXIN EXPOSURE TREATMENT*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
97T: *NEUROTOXIN EXPOSURE TREATMENT*	-	16.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-

A. Mission Description and Budget Item Justification

Congressional Interest Item funding for Neurotoxin Exposure Treatment.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017
Congressional Add: Peer-Reviewed Neurotoxin Exposure Treatment Parkinsons Research Program	16.000	-
FY 2016 Accomplishments: Neurotoxin Exposure Treatment Parkinsons Research Program		
Congressional Adds Subtotals	16.000	-

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: FY 2018 Army											Date: May 2017	
Appropriation/Budget Activity 2040 / 3					R-1 Program Element (Number/Name) PE 0603002A / *Medical Advanced Technology*				Project (Number/Name) ET5 / *Adv Tech Dev in Clinical & Rehabilitative Medicine*			
COST ($ in Millions)	**Prior Years**	**FY 2016**	**FY 2017**	**FY 2018 Base**	**FY 2018 OCO**	**FY 2018 Total**	**FY 2019**	**FY 2020**	**FY 2021**	**FY 2022**	**Cost To Complete**	**Total Cost**
ET5: *Adv Tech Dev in Clinical & Rehabilitative Medicine*	-	0.000	11.656	9.958	-	9.958	9.151	4.893	5.057	6.766	-	-

Note

In Fiscal Year (FY) 2017 the Clinical and Rehabilitative Medicine funding will move from Project 840 to Project ET5.

A. Mission Description and Budget Item Justification

Project ET5 conducts validation studies on safety and effectiveness of drugs, biologics (medical products derived from living organisms), medical devices, and medical procedures intended to minimize long-term effects from battlefield injuries; advanced technology development and clinical studies for treatment of ocular and visual system traumatic injury; and restoration of function and appearance by regenerating skin, muscle, nerve, vascular and bone tissue in battle-injured casualties.

Research conducted in this Project focuses on Clinical and Rehabilitative Medicine

All research is conducted in compliance with Food and Drug Administration (FDA) requirements for licensure of medical products for human use.

Promising efforts identified through applied research conducted under Program Element (PE) 0602787, Project ET4, are further matured under this Project.

The cited work is consistent with the Assistant Secretary of Defense, Research and Engineering Science and Technology, focus areas and the Army Modernization Strategy.

Work in this Project is performed by the United States Army Institute of Surgical Research (USAISR), Joint Base San Antonio, TX; the Armed Forces Institute of Regenerative Medicine (AFIRM), and Multiple Institutions across the United States.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Clinical and Rehabilitative Medicine	-	11.656	9.958
Description: This effort supports clinical studies to advance treatment and restoration strategies of traumatically-injured tissues, to include skin, nerve, bone and ocular (eye) tissue to ultimately restore function and appearance. Areas of interest for regenerative medicine include healing without scarring, repair of compartment syndrome (muscle and nerve damage following reduced blood flow caused by swelling), replacement skin, facial reconstruction and vision restoration. ***FY 2017 Plans:*** Will execute preclinical studies of drug delivery, diagnostic, tissue repair, and/or treatment strategies for traumatic eye injury and assess the preclinical safety and efficacy of promising strategies to facilitate clinical translation. Will conduct early human			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Army		Date: May 2017
Appropriation/Budget Activity 2040 / 3	**R-1 Program Element (Number/Name)** PE 0603002A / *Medical Advanced Technology*	**Project (Number/Name)** ET5 / *Adv Tech Dev in Clinical & Rehabilitative Medicine*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
clinical trials to ensure the safety of an ocular bandage. Will further advance novel drug delivery, diagnostic, reconstructive, and regenerative strategies including the combination of novel biological materials and cell-based therapies (e.g. stem cells) to restore soft (e.g. skin, muscle, nerve, vascular) and bone tissue form and function toward clinical translation; will enhance promising approaches from FY 2016 by performing preclinical safety and efficacy evaluation of candidate strategies for burns, scarless wound healing, bone and soft tissue repair for application to the eyes, extremities, face, genitalia and abdominal body regions. Will continue to advance improved monitoring technologies for tissue rejection during hand and face transplant procedures and improved vascular technologies that reduce the requirement for vein harvest. ***FY 2018 Plans:*** Will advance early human clinical trials to ensure the safety and efficacy of an ocular bandage designed to rescue vision post-injury. Will conduct pre-clinical investigation of engineered skin substitutes for regeneration of functional skin without scarring. Will conduct pre-clinical trials of devices for repairing traumatic injury to craniofacial and extremity tissues. Will evaluate candidate biological therapies and drugs for reduced need of immunosuppressive (inhibition of the immune response) therapies following hand and face transplants. Will advance translation of candidate technologies and biologics that create a wound environment more conducive to bone healing.			
Accomplishments/Planned Programs Subtotals	-	11.656	9.958

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: FY 2018 Army					Date: May 2017							
Appropriation/Budget Activity 2040 / 3					R-1 Program Element (Number/Name) PE 0603002A / *Medical Advanced Technology*				Project (Number/Name) FH4 / *Force Health Protection - Adv Tech Dev*			
COST ($ in Millions)	**Prior Years**	**FY 2016**	**FY 2017**	**FY 2018 Base**	**FY 2018 OCO**	**FY 2018 Total**	**FY 2019**	**FY 2020**	**FY 2021**	**FY 2022**	**Cost To Complete**	**Total Cost**
FH4: *Force Health Protection - Adv Tech Dev*	-	1.232	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-

Note

Starting in Fiscal Year (FY) 2017 the FH4 funding and research will be merged into Project MM3.

A. Mission Description and Budget Item Justification

This Project maturates, demonstrates, and supports enhanced Force Health Protection of Soldiers against threats in military operations and training. Health-monitoring tools are matured to rapidly identify deployment stressors that affect the health of Joint Forces. The key databases supporting this program are the Millennium Cohort Study and the Total Army Injury and Health Outcomes Database. These databases and systems enhance the Department of Defense (DoD) ability to monitor and protect against adverse changes in health, especially psychological/ mental health effects caused by changes in brain function. Force Health Protection work is conducted in close coordination with the Department of Veterans Affairs. This Project is maturing the development of holistic health monitoring (e.g., development of neuropsychological evaluation methods) and validating subclinical signs and symptoms correlating to medical records, diagnosed diseases, and mortality rates across a Soldier's career. These databases allow for the examination of interactions of psychological (mental) stress and other deployment and occupational stressors that affect Warfighter health behaviors.

This Project contains no duplication with any effort within the Military Departments and includes direct participation by other Services. The cited work is fully coordinated with Natick Soldier Research Development Engineering Command (NSRDEC), Natick, MA.

The cited work is consistent with the Assistant Secretary of Defense, Research and Engineering Science and Technology, focus areas and the Army Modernization Strategy.

Work in this Project is performed by the United States Army Center for Environmental Health Research (USACEHR), Fort Detrick, MD; the United States Army Research Institute of Environmental Medicine (USARIEM), Natick, MA; and the Naval Health Research Center (NHRC), San Diego, CA.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Health Research	1.232	-	-
Description: This effort develops and validates novel tools and strategies to advance individualized operational exposure dosimetry (measures of exposure) and establish dose-response links between operational exposures and neurological (of or about the nerves and nervous system) and physical health. Dosimetry tools may include new technologies, human biomarkers (indicator of a process, event, condition or change within the body), objective physiologic markers, physiological) modeling, and validated algorithms to evaluate the health effects of military service, including deployments, and methods to detect a Warfighters			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Army		Date: May 2017
Appropriation/Budget Activity 2040 / 3	**R-1 Program Element (Number/Name)** PE 0603002A / *Medical Advanced Technology*	**Project (Number/Name)** FH4 / *Force Health Protection - Adv Tech Dev*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
exposure to environmental contamination and/or toxic substances, e.g. toxic industrial chemicals (TIC). Starting in FY17 effort will be merged into Project MM3. ***FY 2016 Accomplishments:*** Advance and deliver innovative tools, approaches, and models for detecting and measuring a Warfighters' exposure to potentially toxic substances during operations. Provide dose-response links between operational exposures and neurological and physical health / well-being. Provide models for predicting the likelihood of neurological or physical injury as a result of operational exposure(s) to TICs. Deliver evidence-based guidance to inform policy makers to refine guidelines for individualized operational exposure dosimetry linked to neurological and physical injury.			
Accomplishments/Planned Programs Subtotals	1.232	-	-

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: FY 2018 Army			Date: May 2017
Appropriation/Budget Activity 2040 / 3	R-1 Program Element (Number/Name) PE 0603002A / *Medical Advanced Technology*	Project (Number/Name) MM2 / *MEDICAL ADVANCE TECHNOLOGY INITIATIVES (CA)*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
MM2: *MEDICAL ADVANCE TECHNOLOGY INITIATIVES (CA)*	-	8.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	-	-

A. Mission Description and Budget Item Justification

Congressional Interest Item funding for Medical Advanced Technology Initiatives.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017
Congressional Add: Military Burn Trauma Research Program	8.000	-
FY 2016 Accomplishments: Military Burn Trauma Research Program		
Congressional Adds Subtotals	8.000	-

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: FY 2018 Army			Date: May 2017
Appropriation/Budget Activity 2040 / 3	R-1 Program Element (Number/Name) PE 0603002A / *Medical Advanced Technology*	Project (Number/Name) MM3 / *Warfighter Medical Protection & Performance*	

COST ($ in Millions)	Prior Years	FY 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
MM3: *Warfighter Medical Protection & Performance*	-	18.098	20.816	20.218	-	20.218	17.521	17.094	18.430	19.251	-	-

Note

Starting in Fiscal Year (FY) 2017 the FH4 funding and research will be merged into Project MM3.

A. Mission Description and Budget Item Justification

This Project supports the Medical and Survivability technology areas of the future force with laboratory validation studies and field demonstrations of biomedical products designed to protect, sustain, and enhance Soldier performance in the face of myriad environmental and physiological (human physical and biochemical functions) stressors and materiel hazards encountered in training and operational environments. This effort focuses on demonstrating and transitioning technologies as well as validated tools associated with biomechanical-based health risks, injury assessment and prediction, Soldier survivability, and performance during continuous operations. The four main thrust areas are: 1) Physiological Health; 2) Environmental protection; 3) Injury Prevention and Reduction; and 4) Psychological (mental) Health and Resilience.

This Project contains no duplication with any effort within the Military Departments and includes direct participation by other Services. The cited work is fully coordinated with Natick Soldier Research Development (NSRDEC), Natick, MA.

The cited work is consistent with the Assistant Secretary of Defense, Research and Engineering Science and Technology, focus areas and the Army Modernization Strategy.

Work in this Project is performed by the United States Army Research Institute of Environmental Medicine (USARIEM), Natick, MA, and United States Army Aeromedical Research Laboratory (USAARL), Fort Rucker, AL.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: Physiological (human physical and biochemical functions) Health and Environmental Protection (Sleep Research/ Environmental Monitoring)	2.736	5.753	7.214
Description: This effort supports and matures laboratory prototypes, nutritional interventions, and decision aids for the validation of physiological status and prediction of Soldier performance in extreme environments. This effort supports Capability Demonstration 1.b, Force Protection--Warfighter and Small Unit in FY2014-2016 and also supports capability demonstrations in the area of decreasing Warfighter physical burden in FY2014-2016.			
FY 2016 Accomplishments:			

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Verify that nutritional approaches enhance recovery of brain function after injury. Demonstrate dining hall interventions that improve Warfighter diet quality. Validate models that can accurately predict recovery and safe return-to-duty. ***FY 2017 Plans:*** Will assess the impact of nutritionally optimized ration items on body composition and physiological status in Warfighters. Will determine the effectiveness of nutritional interventions (e.g. zinc, Omega-3 polyunsaturated fatty acids, etc.) for accelerating recovery from impact-acceleration head injury. Will begin modeling of cognitive performance with caffeine consumption based on reaction time data from laboratory studies. Will characterize intra-individual responsiveness under operationally relevant sleep-loss conditions. Assess physiological metrics (or biomarkers) that are associated with resilience and long term military career success. ***FY 2018 Plans:*** Will evaluate the impact of nutritionally optimized ration items on body composition and physiological status in Warfighters. Will demonstrate the effectiveness of nutrient and dietary strategies (e.g., omega-3 polyunsaturated fatty acids, zinc, and hydration) for reducing the vulnerability to and/or accelerating the recovery from mild TBI. Will validate and transition a novel mathematical method for estimating thermal-work strain from non-invasive measures such as heart rate, skin temperature, and heat flux. Will deliver a testable Cold Weather Ensemble Decision Aid (CWEDA), to compare different clothing ensembles for predicting cold weather endurance. Will perform initial field trials and demonstrations of Real Time Physiological Status Monitoring (RT-PSM) for the Chemical, Biological, Radiological, Nuclear and Explosive (CBRNE) and United States Marine Corps (USMC) communities. The RT-PSM system will enable real-time health surveillance and immediate recognition, characterization, and response to changes in force health status. Will mature an anatomically-correct Finite Element Thermoregulatory Model (FETM), which is used to simulate regional thermal differences in human physiology (e.g., sweat rate, heat production) and clothing (e.g., thermal and vapor resistance), as well as human-clothing thermal interactions, enabling individualized predictions of human responses to environmental, mission, and load carriage stresses.			
Title: Environmental Health and Protection - Physiological (human physical and biochemical functions) Awareness Tools and Warrior Sustainment in Extreme Environments.	1.759	4.024	2.953
Description: This effort supports and maturates non-invasive technologies, decision-aid tools, and models to enhance Warfighter protection and sustainment across the operational spectrum. This effort provides the scientific basis for developing focused heating and cooling solutions to maintain fine motor dexterity, core temperature, and optimize physical and cognitive performance during cold-weather and hot-humid operations. ***FY 2016 Accomplishments:*** Validate biomarkers of heat injured organ damage to clinical outcome measures. Validate effectiveness of interventions including targeted drug treatments for recovery from heat injury. Transition altitude sickness, acclimatization and task performance models			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Army		Date: May 2017
Appropriation/Budget Activity 2040 / 3	**R-1 Program Element (Number/Name)** PE 0603002A / *Medical Advanced Technology*	**Project (Number/Name)** MM3 / *Warfighter Medical Protection & Performance*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
to physiological status monitoring system(s) for end-user field validation studies. Refine localized heating strategies to improve hand dexterity and develop a militarily-relevant dexterity assessment method for cold weather operations and provide policy guidance for validated intervention strategies. ***FY 2017 Plans:*** Will provide evidence-based practice recommendations; continue to validate more specific biomarkers of physiological adaptation, and mathematical models for optimizing health and performance against combinations of environmental threats. Will increase finger blood flow, fine-motor dexterity and thermal comfort using facial heating during exposure to cold air for integration into a microclimate heating prototype. Will validate a tool for modernizing dexterity assessment. The assessment instrument will capture many embedded cognitive and sensory components of dexterity such as problem solving, planning, attention, vision, tactile sensation, and proprioception (sense of how our bodies are positioned). ***FY 2018 Plans:*** Will provide validated evidence-based practice recommendations for biomarkers of physiological adaptation and mathematical models for optimizing health and performance against combinations of environmental threats. Will develop a portable, field-detection device capable of diagnosing target organ injury following exposure to extreme environments and assessing risk of adverse health effects and informing command return-to-duty decisions. Will develop a mobile application for identifying megacity chemical threats and adverse health effects and informing Command decisions, Will integrate patented skin temperature feedback technology into current microclimate cooling system. Will improve cooling efficiency by increasing the microclimate cooling surface area in direct contact with skin.			
Title: Injury Prevention and Reduction ***Description:*** This effort supports and validates injury prediction tools and return-to-duty assessments for brain, spine, and chest injury from blast, blunt, and ballistic impact. This effort also addresses need for validated aeromedical standards and strategies to enable aircrew to effectively fight, navigate, & land under a range of degraded visual environments and provide aeromedical return to duty guidelines after neurosensory injury (deficits in the nervous system control of the senses: vision, hearing, taste, smell, and touch). ***FY 2016 Accomplishments:*** Work with combat developers to provide active and passive hearing protection standards. Refine and validate model(s) for predicting effects of hearing loss on speech intelligibility with hearing protection. Refine standards for improved sensory system countermeasures to be used by aircrew in degraded visual environments. Validate computational models that predict the effects of the primary blast wave on the face and eyes and incorporate into a decision aid for transition to commanders. ***FY 2017 Plans:***	4.101	4.842	5.299

Exhibit R-2A, RDT&E Project Justification: FY 2018 Army		Date: May 2017
Appropriation/Budget Activity 2040 / 3	**R-1 Program Element (Number/Name)** PE 0603002A / *Medical Advanced Technology*	**Project (Number/Name)** MM3 / *Warfighter Medical Protection & Performance*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Will validate objective assessment criteria for the prediction of central and peripheral acoustic and hearing-balance sensory nerve injury. Will validate metrics that predict the type and severity of blast induced eye and visual pathway injuries. Will develop and validate methodology and standards to guide the design of Warfighter eye protection compatible with modern military systems in aviation and enable optimal visual performance. Disseminate top clinical factors (disease/injuries) that impact aircrew performance and provide recommendations to update policy papers. Will monitor and quantify the long-term effects of neurosensory injury on military occupational performance and the long term consequences of retaining Warfighters with previous neurosensory injuries. Will continue surveillance and documentation of best practices to improve and transition an updated neurosensory performance return to duty toolkit. ***FY 2018 Plans:*** Will collect human middle ear reflex data to validate objective auditory injury risk models. Will evaluate metrics that predict the type and severity of blast-induced eye and visual pathway injuries. Will provide improved auditory protection standards and guidelines for speech discrimination, attenuation, and localization properties of active and passive hearing protection systems. Will validate objective assessment criteria for the prediction of protective capabilities of current Authorized Protective Eyewear List (APEL) spectacles and goggles resulting from blast-wave forces using multiple low and high energy pounds per square inch (PSI) forces. Will provide improved aeromedical standards for human performance during degraded visual environments. Will evaluate pilot metrics under selected visual and physiological stress conditions. Will evaluate how components of soldier tasks contribute to musculoskeletal injury and incorporate these data into predictive musculoskeletal injury risk models for improved injury prevention guidance. Will finalize and publish the Return to Duty (RTD) Toolkit and distribute it to clinical providers to enable RTD decisions. Will publish provisional biomedical-based spinal injury criteria and assessment methodologies for two types of vertebral body fractures that seated occupants of military vehicles experience during vertical exposure.			
Title: Psychological Health and Resilience	9.502	5.082	3.667
Description: This effort supports and validates neurocognitive (relating to or involving the central nervous system and cognitive abilities) assessment and brain injury detection methods; and validates tools and preclinical methods to treat post-traumatic stress disorder in a military population. This effort also supports validation of interventions in Warfighters for post-traumatic stress disorder (PTSD), validation of biomarkers of individual PTSD symptoms, validation of methods to follow effectiveness of PTSD treatments, validation of neuroprotective (protection of nerves and nervous system) interventions and validation of strategies to prevent neurocognitive deficits (reduced ability to learn and comprehend) and symptomatology associated with brain injury. ***FY 2016 Accomplishments:*** Continue to validate previously developed strategies to reduce vulnerability to concussive injury during blast and impact exposures and promote recovery from concussion. Initiate investigation into the correlation of detailed PTSD symptomatology/ behavioral data with deoxyribonucleic acid (DNA), protein and food breakdown products (genomic, proteomic, and metabolic) biomarkers for stratification of PTSD into subtypes (each PTSD patient may not have the exact same list of symptoms so those			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Army		Date: May 2017
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B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
that exhibit similar symptoms would be a categorical subtypes). Collect specimens pre- and post-treatment for identification of blood biomarkers associated with treatment response and identification of predictive markers associated with successful exposure therapy treatment. Continue collaborative support for research and data analysis with the Army University Affiliated Research centers, the University of California Santa Barbara Institute for Collaborative Biotechnologies and Systems Biology Enterprise. ***FY 2017 Plans:*** Will continue to expand the Systems Biology Enterprise PTSD biomarker research to identify the impact of treatment upon PTSD disease biomarkers and will begin relating biomarker change to specific interventions toward development of prescriptive intervention regimen. Will continue human research funding of randomized controlled trials of pharmacologic PTSD intervention (Rilouzal). Will continue animal model research focused upon identification of molecular level intervention targets for PTSD treatment and matching with available Food and Drug Administration (FDA) approved drugs (for off label use or Investigational New Drug (IND) consideration). Will produce a prototype mathematical model for concussion risk prediction (links likelihood of concussion to an impact or blast exposure) based on animal study data, data from high school and collegiate athletes, input from breacher blast-exposure studies and in-theater measurements. ***FY 2018 Plans:*** Will expand the Systems Biology Enterprise PTSD biomarker research effort to focus on identifying the impact of treatment on PTSD disease biomarkers and to relate changes in biomarkers to specific interventions toward the development of a prescriptive intervention regimen. Will validate at least one novel neurocognitive target of aggression and a corresponding intervention tool. Will develop and test a gaming-based neurocognitive optimization application. Will validate a mobile app platform by directly comparing response rates and behavioral health benchmarks across standard paper-and-pencil and app-based behavioral health assessments (both individual and unit-based).			
Title: Health Research ***Description:*** This effort develops and validates novel tools and strategies to advance individualized operational exposure dosimetry (measures of exposure) and establish dose-response links between operational exposures and neurological and physical health. Dosimetry tools may include new technologies, human biomarkers objective physiologic markers, physiological modeling, and validated algorithms to evaluate the health effects of military service, including deployments, and methods to detect a Warfighters exposure to environmental contamination and/or toxic substances, e.g. toxic industrial chemicals. The funding for this research effort was previously in Project FH4 and moved to Project MM3 in FY17. ***FY 2017 Plans:*** Will quantify dose-response relationships to operationally-relevant exposures in military personnel population specifically to permethrin (synthetic chemical, an insecticide and insect repellent) and polycyclic aromatic compounds (created when products like coal, oil, gas, and garbage are burned but the burning process is not complete). Will provide model parameters	-	1.115	1.085

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
for assessment of real-time personal dose levels to operationally relevant exposures among the high risk military job population subgroups. Will document the specific patterns of health outcomes following exposure to permethrin and other operationally relevant chemicals. ***FY 2018 Plans:*** Will quantify dose-response relationships to operationally-relevant exposures of permethrin (a synthetic chemical found in insect repellants) and polycyclic aromatic compounds (created from the incomplete combustion of animal or plant matter, or carbon fuels, such as coal) in the military personnel population. Will provide pertinent model parameters for the assessment of real-time personal dose levels to operationally relevant exposures among the high-risk military job population subgroups. Will evaluate longer-term neurological and/or physical health trajectories associated with operationally relevant exposures during military service.			
Accomplishments/Planned Programs Subtotals	18.098	20.816	20.218

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A