Exhibit R-2, RDT&E Budget Item Justification: PB 2021 Army											Date: February 2020	
Appropriation/Budget Activity 2040: *Research, Development, Test & Evaluation, Army I* BA 2: *Applied Research*					R-1 Program Element (Number/Name) PE 0602787A *I Medical Technology*							
COST ($ in Millions)	**Prior Years**	**FY 2019**	**FY 2020**	**FY 2021 Base**	**FY 2021 OCO**	**FY 2021 Total**	**FY 2022**	**FY 2023**	**FY 2024**	**FY 2025**	**Cost To Complete**	**Total Cost**
Total Program Element	-	87.229	112.955	95.496	-	95.496	95.558	100.807	102.483	103.020	0.000	697.548
869: *Warfighter Health Prot & Perf Stnds*	-	38.883	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	38.883
870: *Dod Med Def Ag Inf Dis*	-	18.457	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	18.457
874: *Cbt Casualty Care Tech*	-	11.297	0.869	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	12.166
BS7: *Medical Technology (CA)*	-	0.000	13.800	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	13.800
ET4: *Appl Resch in Clinical and Rehabilitative Medicine*	-	9.705	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	9.705
MK4: *Warfigher Health Applied Rsch Technology*	-	0.000	38.392	29.843	-	29.843	30.441	37.412	38.179	39.818	0.000	214.085
MM4: *Cbt Casualty Care Applied Rsch Technology*	-	0.000	17.909	19.424	-	19.424	20.549	21.025	22.541	22.547	0.000	123.995
MM6: *Medical Technologies to Support Dispersed Ops Tech*	-	0.000	12.109	14.417	-	14.417	12.940	14.257	14.016	13.001	0.000	80.740
MM8: *Infectious Diseases and Applied Rsch Technology*	-	0.000	21.661	24.851	-	24.851	25.459	25.021	24.603	24.610	0.000	146.205
MN1: *Applied Sensory Systems Trauma Technology*	-	0.000	7.615	6.961	-	6.961	6.169	3.092	3.144	3.044	0.000	30.025
VB3: *MEDICAL TECHNOLOGY INITIATIVES (CA)*	-	2.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	2.000
VB4: *System Biology And Network Science Technology*	-	1.383	0.600	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	1.983
XV5: *Medical Capabilities to Support Dispersed Ops*	-	5.504	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	5.504

Note

In Fiscal Year (FY) 2020, Projects in this Program Element (PE) have been realigned as noted on each applicable R-2A.

All FY20 adjustments realign program financial structure to Army Modernization Priorities in support of the National Defense Strategy.

Exhibit R-2, RDT&E Budget Item Justification: PB 2021 Army	Date: February 2020
Appropriation/Budget Activity 2040: *Research, Development, Test & Evaluation, Army* / BA 2: *Applied Research*	**R-1 Program Element (Number/Name)** PE 0602787A / *Medical Technology*

A. Mission Description and Budget Item Justification

This Program Element (PE) supports application of knowledge gained through basic research to refine drugs, vaccines, medical devices, diagnostics, medical practices/ procedures, and other preventive measures essential to the protection and sustainment of Warfighter health. Research is conducted in six principal areas: Combat Casualty Care, Military Operational Medicine, Military Relevant Infectious Diseases, Clinical and Rehabilitative Medicine, Medical Capabilities to Support Dispersed Operations, and Systems Biology/Network Sciences. Projects are coordinated with the Defense Health Agency.

Project 869: Warfighter Health Prot & Perf Stnds
Description: Refines knowledge and technologies on screening tools and preventive measures for post-traumatic stress disorder (PTSD), behavioral health problems (e.g., suicide, substance abuse), and mild traumatic brain injuries; physiological monitors and interventions to protect Warfighters from injuries resulting from operational stress; and exposure to hazardous environments and materials.

Project 870: Dod Med Def Ag Inf Dis
Description: Designs and refines drugs, vaccines, medical diagnostic assays/tests devices, other preventive measures for protection and treatment against naturally occurring infectious diseases as identified by worldwide medical surveillance and military threat analysis.

Project 874: Cbt Casualty Care Tech
Description: Identifies and evaluates drugs, biologics (medical products derived from living organisms), medical devices, and associated clinical practices for field trauma care systems, resuscitation, and life support, with emphasis on provision of prolonged field care when medical evacuation and access to definitive surgical care are delayed. Focus is identification of more effective critical care technologies and clinical practices to treat severe bleeding, traumatic brain injury, burns and other combat related injuries. This Project is coordinated with the Defense Health Agency.

Project ET4: Appl Resch in Clinical and Rehabilitative Medicine
Description: Identifies and evaluates drugs, biologics, medical devices, treatments and diagnostics for post-evacuation restorative, regenerative and rehabilitative care, as well as systems for use by field medics and surgeons for ocular trauma. Research focus is on identifying more effective technologies and protocols to treat ocular injury and visual system dysfunction, as well as laboratory and animal studies for regenerating skin, muscle, nerves, vascular and bone tissues for the care and treatment of wounded Service members.

Project MK4: Warfighter Health Applied Rsch Technology
Description: Refines knowledge and technologies on screening tools and preventive measures for PTSD, behavioral health problems, and mild traumatic brain injuries, physiological monitors, and interventions to protect Warfighters from injuries resulting from operational stress and exposure to hazardous environments and materials. Also conducts research on medically valid testing devices and predictive models used for the refinement of Warfighter protective equipment.

Project MM4 Cbt Casualty Care Applied Rsch Technology

Exhibit R-2, RDT&E Budget Item Justification: PB 2021 Army	Date: February 2020
Appropriation/Budget Activity 2040: *Research, Development, Test & Evaluation, Army I* BA 2: *Applied Research*	**R-1 Program Element (Number/Name)** PE 0602787A *I Medical Technology*

Description: Identifies and evaluates drugs, biologics (medical products derived from living organisms), medical devices and associated clinical practices for field trauma care, resuscitation, and life support with emphasis on provision of prolonged field care when medical evacuation and access to definitive surgical care is delayed. Focus is identification of more effective critical care technologies and clinical practices to treat severe bleeding, traumatic brain injury, burns and other combat related injuries.

Project MM6: Medical Technologies to Support Dispersed Ops Technology
Description: Medical Robotic and Autonomous Systems (Med-RAS) - Research to develop the ability to deliver emergency resupply of Medical material including repair parts peculiar to medical equipment by ground or air, such as blood products, and, utilization of autonomous platforms to perform medical treatment and medical evacuations in dispersed and multi-domain battle environments.

Project MM8: Infectious Diseases Applied Rsch Technology
Description: Applied research to design and refine drugs, vaccines, and other medical countermeasures against naturally occurring infectious diseases as identified by worldwide medical surveillance and capability needs assessments.

Project MN1: Applied Sensory Systems Trauma Technology
Description: Research to understand the influence of stress on the effectiveness of pain relief drugs (analgesics). This Project conducts laboratory and animal studies for the purpose of developing novel, non-opioid drugs to treat pain in the austere battlefield environment with minimal side effects.

Project VB3: Medical Technology Initiatives (CA)
Description: Congressional Special Interest funding for Medical Technology applied research.

Project VB4: System Biology and Network Science Technology
Description: Includes strategic oversight, direction and management of applied research in integrative systems biology of military relevant conditions, and the Systems Biology Collaboration Center (SBCC). The Sys Bio Cube (a biomedical research data integration and analysis system), managed by the SBCC, provides the ability for multi-site collaborative efforts to integrate, visualize and evaluate complex data using innovative technologies. Post-Traumatic Stress Disorder and coagulopathy (a disorder that impairs the blood's ability to form clots) projects have utilized the systems biology analytical tools and visualization within the Sys Bio Cube to inform the development of prognostic indicators, objective diagnostics, and improved and personalized therapeutic strategies more quickly than non-systems approaches. The SBCC also serves as a US Army Medical Research and Development Command (USAMRDC) resource for data sharing and data management for maximizing the value of all research efforts across the Command.

Project XV5: Medical Capabilities to Support Dispersed Ops
Description: Research to design, develop, and improve Med-RAS, Virtual Health for telemedicine and remotely delivered patient care, and unmanned capabilities for providing or supporting combat casualty care in far-forward and dispersed geographic environments. This research includes the design of semi-autonomous and closed-loop combat casualty triage, diagnosis, physiological monitoring, therapeutic intervention, casualty evacuation, telemedicine/ tele-mentoring and emergency medical resupply technologies for integration with emerging multi-purpose Army Robotics and Autonomous Systems (RAS) and Virtual Health/Telemedicine delivery platforms while optimizing the medical logistic footprint.

Exhibit R-2, RDT&E Budget Item Justification: PB 2021 Army	Date: February 2020
Appropriation/Budget Activity 2040: *Research, Development, Test & Evaluation, Army I* BA 2: *Applied Research*	**R-1 Program Element (Number/Name)** PE 0602787A *I Medical Technology*

The cited work is consistent with the Under Secretary of Defense for Research and Engineering science and technology focus areas and the Army Modernization Strategy.

Work in this PE is performed by the United States Army Medical Research and Development Command (USAMRDC), Fort Detrick, MD.

All medical applied research is conducted in compliance with Food and Drug Administration (FDA) or Environmental Protection Agency (EPA) regulations. The FDA requires thorough testing in animals (preclinical testing) to ensure safety and, where possible, effectiveness prior to evaluation in controlled human clinical trials (upon transition to Advanced Technology Development). This PE focuses on research and refinement of technologies such as product formulation and purification and laboratory test refinement with the aim of identifying candidate solutions. This work often involves testing in animal models. The EPA also requires thorough testing of products, such as sterilants, disinfectants, repellents, and insecticides to ensure the environment is adequately protected before these products are licensed for use. Program refinement and execution is 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 Defenses (DoD) biomedical research community, as well as their associated enabling research areas.

B. Program Change Summary ($ in Millions)	FY 2019	FY 2020	FY 2021 Base	FY 2021 OCO	FY 2021 Total
Previous President's Budget	92.003	99.155	94.786	-	94.786
Current President's Budget	87.229	112.955	95.496	-	95.496
Total Adjustments	-4.774	13.800	0.710	-	0.710
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	13.800			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-2.510	-			
• SBIR/STTR Transfer	-2.264	-			
• Adjustments to Budget Years	-	-	0.710	-	0.710

Congressional Add Details ($ in Millions, and Includes General Reductions)	FY 2019	FY 2020
Project: BS7: *Medical Technology (CA)*		
Congressional Add: *Military Force Vector Borne Health Protection*	-	5.000
Congressional Add: *Heat Stress on Female Soldiers*	-	2.000
Congressional Add: *Burn Patient Transfer System*	-	2.000

Exhibit R-2, RDT&E Budget Item Justification: PB 2021 Army	Date: February 2020
Appropriation/Budget Activity 2040: *Research, Development, Test & Evaluation, Army I* BA 2: *Applied Research*	**R-1 Program Element (Number/Name)** PE 0602787A *I Medical Technology*

Congressional Add Details ($ in Millions, and Includes General Reductions)	FY 2019	FY 2020
Congressional Add: *Musculoskeletal Injury and Bone and Muscle Adaption for Military Physical Training*	-	4.800
Congressional Add Subtotals for Project: BS7	-	13.800
Project: VB3: *MEDICAL TECHNOLOGY INITIATIVES (CA)*		
Congressional Add: *Peer-Reviewed Neurotoxin Exposure Treatment Parkinson?s Research Program*	2.000	-
Congressional Add Subtotals for Project: VB3	2.000	-
Congressional Add Totals for all Projects	2.000	13.800

Change Summary Explanation

Funds reprogrammed out for higher priority Army requirements.

Exhibit R-2A, RDT&E Project Justification: PB 2021 Army			Date: February 2020
Appropriation/Budget Activity 2040 / 2	R-1 Program Element (Number/Name) PE 0602787A / *Medical Technology*	Project (Number/Name) 869 / *Warfighter Health Prot & Perf Stnds*	

COST ($ in Millions)	Prior Years	FY 2019	FY 2020	FY 2021 Base	FY 2021 OCO	FY 2021 Total	FY 2022	FY 2023	FY 2024	FY 2025	Cost To Complete	Total Cost
869: *Warfighter Health Prot & Perf Stnds*	-	38.883	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	38.883

Note

In Fiscal Year 2020 (FY20) this Project is being realigned to:
Program Element (PE) 0602787A Medical Technology
* Project MK4 Warfighter Health Applied Rsch Technology

A. Mission Description and Budget Item Justification

This Project conducts research to prevent and protect Warfighters from training and operational injuries; refine mechanisms for detection of physiological (human physical and biochemical function) and psychological (mental) health problems; evaluate hazards to head, neck, spine, eyes, and ears; set the standards for rapid return to duty, and determine new methods to sustain and enhance performance across the operational spectrum. This research provides medical information important to the design and operational use of military systems, and this work forms the basis for behavioral, training, pharmacological (drug actions), and nutritional interventions.

The four main areas of study are:

(1) Physiological Health and Performance
(2) Environmental Health and Protection
(3) Injury Prevention and Reduction
(4) Psychological Health and Resilience

This effort is coordinated with and complimentary to work done in PE0602143A Soldier Lethality Technology and PE0603118A Soldier Lethality Advanced Technology.

The cited work is consistent with the Under Secretary of Defense (Research and Engineering) science and technology focus areas and the Army Modernization Strategy.

FY20 realignments are due to financial restructuring in support of Army Modernization Priorities.

Work in this project is performed by the United States Army Medical Research and Development Command (USAMRDC), Fort Detrick, MD.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2019	FY 2020	FY 2021
Title: Physiological Health and Performance	14.228	-	-

Exhibit R-2A, RDT&E Project Justification: PB 2021 Army		Date: February 2020
Appropriation/Budget Activity 2040 / 2	**R-1 Program Element (Number/Name)** PE 0602787A / *Medical Technology*	**Project (Number/Name)** 869 / *Warfighter Health Prot & Perf Stnds*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2019	FY 2020	FY 2021
Description: This effort evaluates methods for managing and controlling the effects of fatigue on Soldier operational performance and the impact of nutritional strategies to optimize operational performance. Efforts will also contribute to human health and performance optimization and enhancement.			
Title: Environmental Health and Protection ***Description:*** This effort involves applied research addressing the physiological (human physical and biochemical functions) mechanisms of exposure to extreme heat, cold, altitude, and other environmental stressors. This effort establishes scientific evidence for specific and sensitive diagnostics of exertional heat illness to optimize Soldier performance in austere environments. This effort also supports and maturates non-invasive technologies, decision-aid tools, and models to enhance Soldier 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. This effort will develop knowledge and materiel solutions that enable Soldier individualized metabolic assessments and optimization during training and operations.	4.932	-	-
Title: Injury Prevention and Reduction ***Description:*** This effort addresses the Army's number one priority of readiness by improving musculoskeletal injury prevention efforts as well as contributing to preparing Soldiers for potential threats (e.g., directed energy) in and developing capabilities for the multi domain battle environment; evaluates and assesses the effects of repetitive motion during military operations and training on the human body; provides mathematical models to predict the likelihood of physical injuries following continuous operations and muscle fatigue; evaluates current standards for return-to-duty; and establishes improved medical test methods with the goal of rapid return to duty of Soldiers following injury. This effort also develops prevention based strategies and medically based injury criteria for hearing, vestibular (sensory system supporting movement and sense of balance, located in the inner ear), and ocular/facial protection devices, develops and evaluates neurosensory operational risk factors, develops medically based guidelines to assess neurosensory performance and models the effects of acoustic and impact trauma, as stressors on vision and hearing. Efforts will investigate the medical aspects of manned/unmanned teaming (MUM-T) and medical aspects of and protection against directed energy.	6.373	-	-
Title: Psychological Health and Resilience ***Description:*** This effort refines and evaluates early interventions to prevent and reduce combat-related behavioral health problems, including symptoms of Post-traumatic stress disorder (PTSD), depression, anger problems, anxiety, substance abuse, suicide, and other health risk behaviors. This effort assesses and refines tools and interventions to enhance and sustain psychological resilience throughout Soldiers' careers. Efforts also address the health and well-being of families.	13.350	-	-
Accomplishments/Planned Programs Subtotals	38.883	-	-

Exhibit R-2A, RDT&E Project Justification: PB 2021 Army		Date: February 2020
Appropriation/Budget Activity 2040 / 2	**R-1 Program Element (Number/Name)** PE 0602787A / *Medical Technology*	**Project (Number/Name)** 869 / *Warfighter Health Prot & Perf Stnds*

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2021 Army										Date: February 2020		
Appropriation/Budget Activity 2040 / 2					R-1 Program Element (Number/Name) PE 0602787A / *Medical Technology*				Project (Number/Name) 870 / *Dod Med Def Ag Inf Dis*			
COST ($ in Millions)	**Prior Years**	**FY 2019**	**FY 2020**	**FY 2021 Base**	**FY 2021 OCO**	**FY 2021 Total**	**FY 2022**	**FY 2023**	**FY 2024**	**FY 2025**	**Cost To Complete**	**Total Cost**
870: *Dod Med Def Ag Inf Dis*	-	18.457	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	18.457

Note

In Fiscal Year 2020 (FY20), this Project is being realigned to:
Program Element (PE) 0602787A Medical Technology
* Project MM8 Infectious Diseases and Applied Rsch Technology

A. Mission Description and Budget Item Justification

This Project conducts applied research for medical countermeasures to naturally occurring infectious diseases that pose a significant threat to the operational effectiveness of forces deployed outside the United States. Effective preventive countermeasures (protective/therapeutic drugs and vaccines and insect repellents and traps) protect the Force from disease and sustain operations by avoiding the need for evacuations from the theater of operations. Diseases of military importance are malaria, bacterial diarrhea, and viral diseases (e.g., dengue fever and hantavirus). In addition to countermeasures, this project funds refinement of improved diagnostic tools to facilitate early identification of infectious disease threats in an operational environment, informing Commanders of the need to institute preventive actions and improve medical care. Major goals are to integrate genomics (deoxyribonucleic acid (DNA)-based) and proteomics (protein-based) as well as other biotechnologies into the refinement of new concepts for vaccine, drug, and diagnostic candidates.

Research conducted in this Project focuses on the following four areas:

(1) Prevention/Treatment of Parasitic (organisms living in or on another organisms) 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

For the refinement of drugs and biological products, studies in the laboratory and in animal models provide a proof-of-concept for these candidate products, including safety, toxicity (degree to which a substance can damage an organism), and effectiveness, and are necessary to provide evidence to the Food and Drug Administration (FDA) to justify approval for a product to enter into future human subject testing. Additional non-clinical studies are often needed in applied research even after candidate products enter into human testing during advanced technology development, usually at the direction of the FDA, to assess potential safety issues. Drug and vaccine refinement bears high technical risk. Of those candidates identified as promising in initial screens, the vast majority are eliminated after additional safety, toxicity, and/ or effectiveness testing. Similarly, vaccine candidates have a high failure rate, because animal testing may not be a good predictor of human response, and therefore candidate technologies/products are often eliminated after going into human trials. Because of this high failure rate, a continuing effort to identify other potential candidates to sustain a working pipeline of countermeasures is critical for replacing those products that fail in testing.

The cited work is consistent with the Under Secretary of Defense (Research and Engineering) science and technology focus areas and the Army Modernization Strategy.

Exhibit R-2A, RDT&E Project Justification: PB 2021 Army		Date: February 2020
Appropriation/Budget Activity 2040 / 2	**R-1 Program Element (Number/Name)** PE 0602787A / *Medical Technology*	**Project (Number/Name)** 870 / *Dod Med Def Ag Inf Dis*

Work is managed by the United States Army Medical Research and Development Command (USAMRDC) 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.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2019	FY 2020	FY 2021
Title: Applied Research on drugs and vaccines against parasitic diseases ***Description:*** This effort assesses and improves on candidate drugs coming from the Department of Defense (DoD) discovery program and from other collaborations for prevention and treatment of malaria; to counter the continuing spread of drug resistance to current drugs; assesses currently available drugs for use against cutaneous leishmaniasis (a skin-based disease transmitted by sand flies) in animal models; and select the most effective and safe candidates for continued refinement and possible clinical testing. This effort also conducts studies to investigate new candidate vaccines for preventing malaria and selects the best candidate(s) for continued refinement. A highly effective vaccine would reduce or eliminate the use of anti-malarial drugs and would minimize the progression and impact of drug resistance to current/future drugs.	8.550	-	-
Title: Diagnostic Systems and Vector Identification and Control ***Description:*** This effort designs and prototypes new medical diagnostic and surveillance tools for the field, focusing on bedside and field-deployable diagnostic systems and refines interventions that protect Warfighters from biting insects such as sand flies (transmitters of leishmaniasis) and mosquitoes (transmitters of dengue, Japanese encephalitis, malaria, etc.).	0.414	-	-
Title: Viral Threats Research ***Description:*** This effort designs and tests new vaccine candidates in the laboratory against hemorrhagic fever viruses (i.e., dengue virus, Hantaviruses, Lassa fever virus and Crimean-Congo hemorrhagic fever virus) and assesses other non-vaccine technologies to protect against hemorrhagic fever viruses. Efforts also include establishing and maintaining of clinical trial sites worldwide.	4.049	-	-
Title: Bacterial Threats ***Description:*** This effort conducts studies to refine bacterial countermeasures, including vaccine candidates, to prevent diarrhea (most commonly caused by enterotoxigenic E. coli, Campylobacter and Shigella) and scrub typhus (a debilitating mite-borne disease).	5.444	-	-
Accomplishments/Planned Programs Subtotals	18.457	-	-

C. Other Program Funding Summary ($ in Millions)

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2021 Army		Date: February 2020
Appropriation/Budget Activity 2040 / 2	**R-1 Program Element (Number/Name)** PE 0602787A / *Medical Technology*	**Project (Number/Name)** 870 / *Dod Med Def Ag Inf Dis*

C. Other Program Funding Summary ($ in Millions)

Remarks

D. Acquisition Strategy

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2021 Army			Date: February 2020
Appropriation/Budget Activity 2040 / 2	R-1 Program Element (Number/Name) PE 0602787A / *Medical Technology*	Project (Number/Name) 874 / *Cbt Casualty Care Tech*	

COST ($ in Millions)	Prior Years	FY 2019	FY 2020	FY 2021 Base	FY 2021 OCO	FY 2021 Total	FY 2022	FY 2023	FY 2024	FY 2025	Cost To Complete	Total Cost
874: *Cbt Casualty Care Tech*	-	11.297	0.869	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	12.166

Note

In Fiscal Year 2021 (FY21) this Project is being realigned to:
Program Element (PE) 0602787A Medical Technology
* Project MM4 Cbt Casualty Care Applied Rsch Technology

A. Mission Description and Budget Item Justification

Applied technology development of burn recovery optimization technologies: applied technologies for acute burn treatment that remove dead tissue, prevent infection, and protect the wound from further damage until definitive burn care is available; diagnostic technologies to predict skin graft success or failure, identify patients at heightened risk for scarring, and monitor effectiveness of treatment.

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

(1) Damage Control Resuscitation
(2) Combat Trauma Therapies
(3) Combat Critical Care Engineering
(4) Traumatic Brain Injury (TBI)
(5) Prolonged Field Care

All drugs, biological products, and medical devices are refined in accordance with US Food and Drug Administration (FDA) regulations, which govern testing in animals to assess safety, toxicity, and effectiveness and subsequent human subject clinical trials.

Promising efforts identified in this Project are further matured under PE 0603002A (Medical Advanced Technology) / Project 840 (Combat Injury Mgmt).

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

Work in this Project is performed by the US Army Medical Research and Development Command (USAMRDC), Fort Detrick, MD.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2019	FY 2020	FY 2021
Title: Damage Control Resuscitation	3.150	-	-

Exhibit R-2A, RDT&E Project Justification: PB 2021 Army		Date: February 2020
Appropriation/Budget Activity 2040 / 2	**R-1 Program Element (Number/Name)** PE 0602787A / *Medical Technology*	**Project (Number/Name)** 874 / *Cbt Casualty Care Tech*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2019	FY 2020	FY 2021
Description: This effort develops and refines knowledge products (such as clinical practice guidelines, manuals, protocols, studies, and media), materials, and systems for control of internal bleeding; minimizing the effects of traumatic blood loss; preserving, storing, and transporting blood and blood products; and resuscitation following trauma.			
Title: Combat Trauma Therapies ***Description:*** This effort conducts research to enhance the ability to diagnose, stabilize, and accelerate wound healing and repair of damaged tissue for casualties with severe wounds to the face, mouth and extremities. ***FY 2020 Plans:*** Will develop preclinical models in which to evaluate biomarkers of burn wound severity and healing, and will develop preclinical models in which to evaluate new anti-microbial burn wound therapies. ***FY 2020 to FY 2021 Increase/Decrease Statement:*** Funding realigned to Program Element (PE) 0602787A Medical Technology / Project MM4 Cbt Casualty Care Applied Rsch Technology.	4.002	0.829	-
Title: Combat Critical Care Engineering ***Description:*** This effort refines diagnostic and therapeutic medical devices as well as associated algorithms, software, and data-processing systems for resuscitation, stabilization, life support, surgical support and preservation of vital organ function that can be applied across the pre-hospital, operational field setting, and initial definitive care facilities.	1.097	-	-
Title: Traumatic Brain Injury ***Description:*** This effort supports refinement of drug (includes mature drug technologies and those that are FDA approved for other indications) and therapeutic (i.e., novel use of stem cells or selective brain cooling) strategies to manage TBI resulting from battlefield trauma.	1.511	-	-
Title: Prolonged Field Care ***Description:*** This effort performs applied research to study the physiological implications of delayed medical evacuation and limited access to definitive surgical care in severely injured casualties	1.537	-	-
Title: FY 2020 SBIR/STTR Transfer ***Description:*** Funding transferred in accordance with Title 15 USC ?638 ***FY 2020 Plans:***	-	0.040	-

Exhibit R-2A, RDT&E Project Justification: PB 2021 Army		Date: February 2020
Appropriation/Budget Activity 2040 / 2	**R-1 Program Element (Number/Name)** PE 0602787A / *Medical Technology*	**Project (Number/Name)** 874 / *Cbt Casualty Care Tech*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2019	FY 2020	FY 2021
Funding transferred in accordance with Title 15 USC ?638 ***FY 2020 to FY 2021 Increase/Decrease Statement:*** Funding transferred in accordance with Title 15 USC ?638			
Accomplishments/Planned Programs Subtotals	11.297	0.869	-

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2021 Army			Date: February 2020
Appropriation/Budget Activity 2040 / 2	R-1 Program Element (Number/Name) PE 0602787A / *Medical Technology*	Project (Number/Name) BS7 / *Medical Technology (CA)*	

COST ($ in Millions)	Prior Years	FY 2019	FY 2020	FY 2021 Base	FY 2021 OCO	FY 2021 Total	FY 2022	FY 2023	FY 2024	FY 2025	Cost To Complete	Total Cost
BS7: *Medical Technology (CA)*	-	0.000	13.800	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	13.800

Note

Congressional Interest Item funding provided for Medical Technology.

A. Mission Description and Budget Item Justification

Congressional Interest Item funding provided for Medical Technology.

The cited work is consistent with the Under Secretary of Defense for Research and Engineering priority focus areas and the Army Modernization Strategy.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2019	FY 2020
Congressional Add: Military Force Vector Borne Health Protection	-	5.000
FY 2020 Plans: Military Force Vector Borne Health Protection		
Congressional Add: Heat Stress on Female Soldiers	-	2.000
FY 2020 Plans: Heat Stress on Female Soldiers		
Congressional Add: Burn Patient Transfer System	-	2.000
FY 2020 Plans: Burn Patient Transfer System		
Congressional Add: Musculoskeletal Injury and Bone and Muscle Adaption for Military Physical Training	-	4.800
FY 2020 Plans: Musculoskeletal Injury and Bone and Muscle Adaption for Military Physical Training		
Congressional Adds Subtotals	-	13.800

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2021 Army			Date: February 2020
Appropriation/Budget Activity 2040 / 2	R-1 Program Element (Number/Name) PE 0602787A / *Medical Technology*	Project (Number/Name) ET4 / *Appl Resch in Clinical and Rehabilitative Medicine*	

COST ($ in Millions)	Prior Years	FY 2019	FY 2020	FY 2021 Base	FY 2021 OCO	FY 2021 Total	FY 2022	FY 2023	FY 2024	FY 2025	Cost To Complete	Total Cost
ET4: *Appl Resch in Clinical and Rehabilitative Medicine*	-	9.705	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	9.705

Note

In Fiscal Year 2020 (FY20), this Project is being realigned to:
PE 0602787A Medical Technology
* Project MN1 Applied Sensory Systems Trauma Technology

A. Mission Description and Budget Item Justification

This Project identifies and evaluates drugs, biologics (products derived from living organisms), medical devices, treatments and diagnostics for post-evacuation restorative, regenerative and rehabilitative care, as well as systems for use by field medics and surgeons for ocular trauma. Research focuses on identifying more effective technologies and protocols to treat ocular injury and visual system dysfunction, as well as laboratory and animal studies for regenerating skin, muscle, nerves, vascular and bone tissues for the care and treatment of traumatic injury. Research involves extensive collaboration with multiple academic institutions to refine treatments for combat wounds through the Armed Forces Institute of Regenerative Medicine (AFIRM). This Project is coordinated with the Military Departments, Defense Health Agency, and other government organizations to avoid duplication. Research conducted in this Project focuses on Clinical and Rehabilitative Medicine and Battlefield Pain Management.

All drugs, biological products, and medical devices are refined in accordance with Food and Drug Administration (FDA) regulations, which govern testing in animals to assess safety, toxicity, and effectiveness and subsequent human subject clinical trials.

Promising efforts identified in this project are further matured under PE 0603002A (Medical Advanced Technology) / Project ET5 (Adv Tech Dev in Clinical & Rehabilitative Medicine).

The cited work is consistent with the Under 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 Medical Research and Development Command (USAMRDC), Fort Detrick, MD.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2019	FY 2020	FY 2021
Title: Clinical and Rehabilitative Medicine	7.320	-	-
Description: This effort conducts laboratory and animal studies for the purpose of regenerating and restoring traumatically-injured tissues, including skin, muscle, nerve, bone tissue, and the ocular system.			

Exhibit R-2A, RDT&E Project Justification: PB 2021 Army		Date: February 2020
Appropriation/Budget Activity 2040 / 2	**R-1 Program Element (Number/Name)** PE 0602787A / *Medical Technology*	**Project (Number/Name)** ET4 / *Appl Resch in Clinical and Rehabilitative Medicine*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2019	FY 2020	FY 2021
Title: Battlefield Pain Management ***Description:*** This effort performs applied research in laboratory and animal studies to develop novel, non-opioid drugs to treat pain in the austere battlefield environment with minimal side effects.	2.385	-	-
Accomplishments/Planned Programs Subtotals	9.705	-	-

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2021 Army			Date: February 2020
Appropriation/Budget Activity 2040 / 2	R-1 Program Element (Number/Name) PE 0602787A / *Medical Technology*	Project (Number/Name) MK4 / *Warfigher Health Applied Rsch Technology*	

COST ($ in Millions)	Prior Years	FY 2019	FY 2020	FY 2021 Base	FY 2021 OCO	FY 2021 Total	FY 2022	FY 2023	FY 2024	FY 2025	Cost To Complete	Total Cost
MK4: *Warfigher Health Applied Rsch Technology*	-	0.000	38.392	29.843	-	29.843	30.441	37.412	38.179	39.818	0.000	214.085

Note

In Fiscal Year 2020 (FY20), this Project is being realigned from:
Program Element (PE) 0602787A Medical Technology
* Project 869 Warfighter Health Prot & Perf Stnds

A. Mission Description and Budget Item Justification

This Project conducts research to prevent and protect Warfighters from training and operational injuries; refine mechanisms for detection of physiological (human physical and biochemical function) and psychological (mental) health problems; reduce the effects of trauma and promote rapid recovery from acute stress in far forward operational environments; evaluate hazards to head, neck, spine, eyes, and ears; set the standards for rapid return to duty; and determine new methods to sustain and enhance performance and readiness across the operational spectrum. This research provides medical information important to the design and operational use of military systems, and this work forms the basis for behavioral, training, and nutritional interventions.

The four main areas of study are:
(1) Physiological Health and Performance
(2) Environmental Health and Protection
(3) Injury Prevention and Reduction
(4) Psychological Health and Resilience

This effort is coordinated with and complimentary to work done in PE 0602143A Soldier Lethality Technology and PE 0603118A Soldier Lethality Advanced Technology.

The cited work is consistent with the Under Secretary of Defense for Research and Engineering priority focus areas and the Army Modernization Strategy.

Work in this Project is performed by the United States Army Medical Research and Development Command (USAMRDC), Fort Detrick, MD.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2019	FY 2020	FY 2021
Title: Physiological Health and Performance	-	16.920	14.402
Description: This effort evaluates methods for managing and controlling the effects of fatigue on Soldier operational performance and the impact of nutritional strategies to optimize operational performance. Efforts will also contribute to new high-priority medical			

Exhibit R-2A, RDT&E Project Justification: PB 2021 Army		Date: February 2020
Appropriation/Budget Activity 2040 / 2	**R-1 Program Element (Number/Name)** PE 0602787A / *Medical Technology*	**Project (Number/Name)** MK4 / *Warfigher Health Applied Rsch Technology*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2019	FY 2020	FY 2021
investments in human biomedical performance enhancement and medical aspects of manned-unmanned machine teaming (MUM-T). ***FY 2020 Plans:*** Will characterize effects of nutritional energy balance on inflammatory response. Will refine understanding of the environmental influences on eating behavior, to include extreme environmental influences such as heat, cold and altitude. Will determine effects of protein source on protein kinetics and muscle growth and strength. Will evaluate scheduling and fatigue management tools for rotary-wing aviation. Will refine models of aviator risks during Degraded Visual Environment (DVE) operations as a function of neurosensory limitations and physiological condition. Will evaluate degraded Army Manned-Unmanned Teaming operator performance through characterization of medical and work requirements, under operational stressors. Will characterize predictors of resilience during United States Army Special Forces training. Will evaluate exogenous testosterone for maintenance of physiological and psychological performance under conditions of medically relevant hypogonadism (a failure of the gonads, testes in men and ovaries in women, to function properly) induced by high operational tempo military activity. Will provide medical and Solider integration criteria for single-joint exoskeleton to enhance Soldier physical performance in military operations. Will evaluate the effectiveness of slow wave sleep (SWS) augmentation via acoustic stimulation (AS) for enhancing tactical performance and reducing sleepiness during a subsequent period of sustained wakefulness. ***FY 2021 Plans:*** Expeditionary Force Nutrition to Improve Performance ($2.012M) ? Will evaluate the effects of nutritional energy balance on inflammatory response. ? Will refine understanding of the environmental influences on eating behavior, to include extreme environmental influences such as heat, cold and altitude. ? Will evaluate the effects of protein source in protein kinetics and muscle growth and strength. Medical Interventions to Reduce Impact of Fatigue on Performance ($5.356M) ? Will develop a demonstration of the effectiveness of electrical stimulation of the brain for enhancing learning through the consolidation of emotional memories. ? Will evaluate the effectiveness of SWS augmentation via AS for enhancing tactical performance and reducing sleepiness during a subsequent period of sustained wakefulness. Biomedical Performance Enhancement ($6.961M) ? Will evaluate drug-delivered testosterone for maintenance of physiological and psychological performance under conditions of medically relevant hypogonadism (a failure of the gonads, testes in men and ovaries in women, to function properly) induced by high operational tempo military activity.			

Exhibit R-2A, RDT&E Project Justification: PB 2021 Army		Date: February 2020
Appropriation/Budget Activity 2040 / 2	**R-1 Program Element (Number/Name)** PE 0602787A / *Medical Technology*	**Project (Number/Name)** MK4 / *Warfigher Health Applied Rsch Technology*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2019	FY 2020	FY 2021
? Will provide medical and Soldier integration criteria for single-joint exoskeleton to enhance Soldier physical performance in military operations. ? Will evaluate pharmacological strategies for improving Soldier endurance. ***FY 2020 to FY 2021 Increase/Decrease Statement:*** Funding decrease as a result of project realignment.			
Title: Environmental Health and Protection ***Description:*** This effort involves applied research addressing the physiological (human physical and biochemical functions) mechanisms of exposure to extreme heat, cold, altitude, and other environmental stressors. This effort establishes scientific evidence for specific and sensitive diagnostics of exertional heat illness to optimize Soldier performance in austere environments. This effort also supports and matures non-invasive technologies, decision-aid tools, and models to enhance Soldier 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. This effort will develop knowledge and materiel solutions that enable Soldier individualized metabolic assessments and optimization during training and operations. ***FY 2020 Plans:*** Will evaluate human performance in heat, cold and altitude studies which provide physiological monitoring data for algorithms for an integrated Soldier sensor system to sustain lethality, optimize performance, and improve health and readiness. Will evaluate strategies to improve Soldier health, readiness and mission performance through interventions designed to prevent injuries which result from multi-environmental stressors. Will evaluate interventions to reduce environmental injuries in the heat and cold weather operations. Will develop physiologically based algorithm to detect organ and system toxicity post chemical exposure. Will develop physiologically based algorithm to monitor Soldier performance after exposure to toxic chemicals or hazardous materials. Will develop tools that sustain lethality, improve health, and optimize performance to reduce injuries following exposures to heat, cold, terrestrial altitude and toxic chemicals and hazardous materials for squad leaders and mission planners. ***FY 2021 Plans:*** Operational Risk Planning Tools for Battlefield Environmental Threats ($2.773M) ? Will predict, protect, and enhance performance of the Soldier operating in dense urban and subterranean environments, with a focus on respiratory threats, mental and physical performance, and survivability. ? Will develop studies exposing zebrafish to low oxygen conditions, altered temperatures, and psychological stressors (e.g., predator exposure) to evaluate the potential effectiveness of pharmaceutical interventions to optimize performance. ? Will develop an immersive screening task that, in combination with select measures, will be utilized as screening tool for predicting individuals likely to experience impairment.	-	5.925	7.529

Exhibit R-2A, RDT&E Project Justification: PB 2021 Army		Date: February 2020
Appropriation/Budget Activity 2040 / 2	**R-1 Program Element (Number/Name)** PE 0602787A / *Medical Technology*	**Project (Number/Name)** MK4 / *Warfigher Health Applied Rsch Technology*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2019	FY 2020	FY 2021
? Will develop tools to assess medical effects for using personal protective equipment in dense urban and subterranean environments to prevent degraded physical and cognitive performance. Prevention of Soldier Performance Degradation in Extreme Environments (4.687M) ? Will evaluate human performance in heat, cold and altitude studies which provide physiological monitoring data for algorithms for an integrated Soldier sensor system to sustain lethality, optimize performance, and improve health and readiness. ? Will evaluate strategies to improve Soldier health, readiness and mission performance through interventions designed to prevent injuries that result from multi-environmental stressors. ? Will evaluate interventions to reduce environmental injuries in the heat and cold weather operations. ? Will refine and develop tools that sustain lethality, improve health, and optimize performance to reduce injuries following exposures to heat, cold, terrestrial altitude for squad leaders and mission planners. ***FY 2020 to FY 2021 Increase/Decrease Statement:*** Funding increase a result of project realignments.			
Title: Injury Prevention and Reduction	-	7.224	4.170
Description: This effort addresses the Army's number one priority of readiness by improving musculoskeletal injury prevention efforts as well as contributing to preparing Soldiers for potential threats (e.g., directed energy) in and developing capabilities for the multi domain operations environment. It evaluates and assesses the effects of repetitive motion during military operations and training on the human body; provides mathematical models to predict the likelihood of physical injuries following continuous operations and muscle fatigue; evaluates current standards for return-to-duty; and establishes improved medical test methods with the goal of rapid return to duty of Soldiers following injury. This effort also develops prevention-based strategies and medically-based injury criteria for hearing, vestibular (sensory system supporting movement and sense of balance, located in the inner ear), and ocular/facial protection devices; develops and evaluates neurosensory operational risk factors; develops medically based guidelines to assess neurosensory performance and models the effects of acoustic and impact trauma as stressors on vision and hearing. Efforts will investigate the medical aspects of manned unmanned teaming (MUM-T) and medical aspects of and protection against directed energy. ***FY 2020 Plans:*** Will continue to develop injury based head supported mass criteria, behind helmet blunt trauma, behind armor blunt trauma, and blast exposure injury criteria in order to inform next generation integrated head protection systems, vital torso protection systems, and the next generation bomb suit (program of record). Will develop military relevant fitness and return to duty standards for			

Exhibit R-2A, RDT&E Project Justification: PB 2021 Army		Date: February 2020
Appropriation/Budget Activity 2040 / 2	**R-1 Program Element (Number/Name)** PE 0602787A / *Medical Technology*	**Project (Number/Name)** MK4 / *Warfigher Health Applied Rsch Technology*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2019	FY 2020	FY 2021
combat Military Occupational Specialties (MOSs). Will continue to develop medical standards for directed energy threats and develop computational models that will predict organ injury severity and systemic pathological effects. ***FY 2021 Plans:*** Physical Fitness Standards to Prevent Musculoskeletal Injuries ($1.248M) ? Will administer field expedient physical performance tests (PPTs) known to be predictive of performance of common Soldier tasks to Soldiers following lower extremity musculoskeletal injuries. ? Will compare PPT data to known reference values to assess readiness for return to duty (RTD). ? Will use data to assess the prognostic accuracy of PPTs in determining Soldier progression from initial injury to readiness for RTD. Leader Tools to Reduce Musculoskeletal Injury in all Settings ($2.552M) ? Will establish and publish modifiable and non-modifiable factors that impart resilience or contribute to risk for stress fracture and other musculoskeletal injury development during Basic Combat Training (BCT). Leader Decision Aids to Manage Blast Head Injury in All Settings ($0.286M) ? Will determine an objective blood-based biomarker of cognitive status from field studies of blast overpressure and head impact exposures in various heavy weapons military training environments. ***FY 2020 to FY 2021 Increase/Decrease Statement:*** Funding decrease a result of project realignment.			
Title: Psychological Health and Resilience ***Description:*** This effort refines and evaluates tools and early interventions to prevent and reduce the impact of military stressors and combat-related exposures on behavioral health problems, including symptoms of post-traumatic stress disorder (PTSD), depression, anger problems, anxiety, substance abuse, suicide, and other health risk behaviors. This effort assesses and refines tools and interventions to enhance and sustain psychological resilience throughout Soldiers' careers. Efforts also address the health and well-being of families. ***FY 2020 Plans:*** Will continue to assess and characterize risk and resilience markers for Soldiers' psychological and behavioral health. Will identify objective molecular markers for PTSD and PTSD subtypes, treatment response, and return to duty status. Will continue evaluating candidate compounds for treatment of PTSD symptoms through use of a laboratory maintained PTSD animal model. Will develop and test a provider tool kit for standardizing behavioral health provider determinations of Service Members? return to duty status. Will identify and adapt suitable brief acute stress interventions for use in a far-forward setting. Will determine optimal	-	7.506	3.742

Exhibit R-2A, RDT&E Project Justification: PB 2021 Army		Date: February 2020
Appropriation/Budget Activity 2040 / 2	**R-1 Program Element (Number/Name)** PE 0602787A / *Medical Technology*	**Project (Number/Name)** MK4 / *Warfigher Health Applied Rsch Technology*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2019	FY 2020	FY 2021
dosing of Cognitive Bias Modification Training, a computerized treatment that reduces specific cognitive biases (e.g., anxiety-sensitivity, threat, and anger). Will continue to develop and refine evidence-based individual (e.g., self-distancing education, emotion regulation, leadership training) and team-level (e.g., regulation of small-team dynamics) interventions that positively influence behavioral health, resilience, and unit readiness. ***FY 2021 Plans:*** Optimal Delivery of Far Forward Psychological Health Care ($1.835M) ? Will develop content and products to deliver behavioral health services oriented to far forward operational settings for the promotion of rapid recovery from acute stress and other behavioral health issues. ? Will develop readiness tools and recommendations to assist in behavioral health readiness decisions made by unit leaders and medics. ? Will develop clinical practice guidelines medics will follow to address the core behavioral health problems encountered in far-forward settings. ? Will develop neurocognitive optimization and enhancement tools to mitigate health and performance decrements during and following stress exposure (i.e., point of psychological injury). Unit-Level Psychological Interventions to Enhance Performance ($1.823M) ? Will develop and evaluate next-generation bystander intervention training to increase unit member response to high-risk behaviors. ? Will determine how transition points place Soldiers at risk. ? Will conduct assessment of Security Forces Assistance Brigades. ? Will develop a method for assessing military-relevant moral injury concerns. ? Will establish components for enhancing behavioral health leadership skills and develop new training. ***FY 2020 to FY 2021 Increase/Decrease Statement:*** Funding decrease a result of project realignment.			
Title: FY 2020 SBIR/STTR Transfer ***Description:*** Funding transferred in accordance with Title 15 USC ?638 ***FY 2020 Plans:*** Funding transferred in accordance with Title 15 USC ?638 ***FY 2020 to FY 2021 Increase/Decrease Statement:*** Funding transferred in accordance with Title 15 USC ?638	-	0.817	-
Accomplishments/Planned Programs Subtotals	-	38.392	29.843

Exhibit R-2A, RDT&E Project Justification: PB 2021 Army		Date: February 2020
Appropriation/Budget Activity 2040 / 2	**R-1 Program Element (Number/Name)** PE 0602787A / *Medical Technology*	**Project (Number/Name)** MK4 / *Warfigher Health Applied Rsch Technology*

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2021 Army			Date: February 2020
Appropriation/Budget Activity 2040 / 2	R-1 Program Element (Number/Name) PE 0602787A / *Medical Technology*	Project (Number/Name) MM4 / *Cbt Casualty Care Applied Rsch Technology*	

COST ($ in Millions)	Prior Years	FY 2019	FY 2020	FY 2021 Base	FY 2021 OCO	FY 2021 Total	FY 2022	FY 2023	FY 2024	FY 2025	Cost To Complete	Total Cost
MM4: *Cbt Casualty Care Applied Rsch Technology*	-	0.000	17.909	19.424	-	19.424	20.549	21.025	22.541	22.547	0.000	123.995

Note

In Fiscal Year (FY) 2020, this Project is being realigned from:
Program Element (PE) 0602787A Medical Technology
* Project 874 Cbt Casualty Care Tech

A. Mission Description and Budget Item Justification

This Project refines and assesses concepts, techniques, and materiel that improve survivability and treatment outcomes for Warfighters wounded during combat operations and treated under austere field conditions, including prolonged field care, and during medical evacuation. Combat casualty care research addresses control of severe bleeding; resuscitation and stabilization; advanced automated life support systems suitable for use in forward areas, treatment of severe orthopedic injuries, treatment of severe burns, and combat-related brain injury.

Promising efforts identified in this Project are further matured under PE 0603002A (Medical Advanced Technology).

The cited work is consistent with the Under Secretary of Defense (Research and Engineering) science and technology focus areas and the Army Modernization Strategy.

Work in this Project is performed by the Unites States Army Medical Research and Development Command (USAMRDC), Fort Detrick, MD.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2019	FY 2020	FY 2021
Title: Damage Control Resuscitation	-	3.917	-
Description: This effort develops and refines knowledge products (such as clinical practice guidelines, manuals, protocols, studies, and media), materials, and systems for control of internal bleeding; minimizing the effects of traumatic blood loss; preserving, storing, and transporting blood and blood products; and resuscitation following trauma.			
FY 2020 Plans: Will conduct studies to model optimal treatment for acute traumatic coagulopathy (bleeding disorder) using blood products and drugs. Will conduct studies of new platelet preservative solutions to determine ability to rejuvenate platelets during storage. Will develop assays to characterize stem cell effectiveness for trauma care.			
FY 2020 to FY 2021 Increase/Decrease Statement:			

Exhibit R-2A, RDT&E Project Justification: PB 2021 Army		Date: February 2020
Appropriation/Budget Activity 2040 / 2	**R-1 Program Element (Number/Name)** PE 0602787A / *Medical Technology*	**Project (Number/Name)** MM4 / *Cbt Casualty Care Applied Rsch Technology*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2019	FY 2020	FY 2021
Work continues under this same project under program title "Blood and Blood Products."			
Title: Combat Trauma Therapies ***Description:*** This effort conducts research to enhance the ability to diagnose, stabilize, and accelerate wound healing and repair of damaged tissue for casualties with severe burn, facial or extremity wounds. ***FY 2020 Plans:*** Will conduct studies to determine the impact of immune response and life-saving interventions on healing of extremity wounds. Will characterize burn wound fluid proteins to identify potential candidate biomarkers that signal adequacy of wound healing in preclinical animal models. Will evaluate alternative anti-infective/anti-inflammation drugs in animal wound models. Will study technological approaches for diagnosis and treatment of sepsis (life-threatening organ dysfunction caused by the body?s dysregulated response to infection) in a prolonged field care environment. ***FY 2020 to FY 2021 Increase/Decrease Statement:*** This work continues under program titled "Severe Burns" under this same project. Decrease due to realignment of previous Combat Trauma Therapies sub-research areas, with the exception of Severe Burns, to new Prolonged Care research area under this same project.	-	4.265	-
Title: Pre-Hospital Tactical Combat Casualty Care ***Description:*** This effort refines diagnostic and therapeutic medical devices, drugs, and new clinical practices for resuscitation, stabilization, and preservation of vital organ function that can be applied by combat medical personnel in the pre-hospital combat setting. ***FY 2020 Plans:*** Will determine whether current battlefield analgesics (pain relief drugs) produce detrimental cardiovascular effects during hemorrhage. Will determine the systemic effects of tourniquet release after prolonged use and identify potential therapeutic targets. ***FY 2020 to FY 2021 Increase/Decrease Statement:*** This work continues under program titled "Tactical Combat Casualty Care" under this same project.	-	0.866	-
Title: Traumatic Brain Injury (TBI) ***Description:*** This effort supports refinement of drug (includes mature drug technologies and those that are Food and Drug Administration [FDA] approved for other indications) and therapeutic (i.e., novel use of stem cells or selective brain cooling) strategies to manage TBI resulting from battlefield trauma.	-	1.360	-

Exhibit R-2A, RDT&E Project Justification: PB 2021 Army		Date: February 2020
Appropriation/Budget Activity 2040 / 2	**R-1 Program Element (Number/Name)** PE 0602787A / *Medical Technology*	**Project (Number/Name)** MM4 / *Cbt Casualty Care Applied Rsch Technology*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2019	FY 2020	FY 2021
FY 2020 Plans: Will complete animal studies examining neurotherapeutic resuscitation strategies for TBI with polytrauma (injuries to multiple body parts and organ systems). Will complete brain imaging studies using positron emission tomography. Will begin studies evaluating correlative relationships between TBI-induced non-convulsive seizures, TBI-specific biomarkers, and TBI clinical outcomes. Will complete small animal studies evaluating potential beneficial effects of resuscitative endovascular occlusion of the aorta in TBI with polytrauma (will elevate to large animal TBI model if indicated). ***FY 2020 to FY 2021 Increase/Decrease Statement:*** Work continues under program title "Brain Trauma" under the same project.			
Title: Prolonged Care ***Description:*** This effort performs applied research to study the physiological implications of delayed medical evacuation and limited access to definitive surgical care in severely injured casualties. ***FY 2020 Plans:*** Will develop animal models of machine perfusion of vascularly isolated limbs that can be used to evaluate oxygen carrying solutions for limb preservation during extended tourniquet application. Will conduct large animal studies of stem cell products to treat acute respiratory distress syndrome. Will develop and test automated control for partial resuscitative endovascular balloon occlusion of the aorta during application of prolonged cardiovascular support. ***FY 2021 Plans:*** Battlefield sustainment of critical organ function cap set 1 ($3.521M) ? Will perform large animal studies of stem cell products to treat acute respiratory distress syndrome. Future en Route Casualty Care Sustainment System Cap Set ($1.678M) ? Will assess biological effects and safety of new extracorporeal life support technologies (medical devices situated external to the body that provide prolonged organ support in casualties whose vital organs are, due to illness or injury, unable to sustain life). Modular and Automated Battlefield Sustainment of Critical Organ Function Cap Set 2 ($0.880M) ? Will develop sepsis prediction and prolonged field care decision support system. Limb Function Repair and Return to Combat Duty ($0.571M) ? Will evaluate technologies to preserve injured limb tissues and function under prolonged field care conditions. Field Stabilization of Preparation of Evac ($0.493M)	-	7.279	7.186

Exhibit R-2A, RDT&E Project Justification: PB 2021 Army		Date: February 2020
Appropriation/Budget Activity 2040 / 2	**R-1 Program Element (Number/Name)** PE 0602787A / *Medical Technology*	**Project (Number/Name)** MM4 / *Cbt Casualty Care Applied Rsch Technology*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2019	FY 2020	FY 2021
? Will evaluate drug and biological compounds to improve extremity wound healing. ? Will begin evaluation of litter carriage performance and post-carry fatigue effects in prolonged field care environments. ***FY 2020 to FY 2021 Increase/Decrease Statement:*** Funding decrease based on level of effort required.			
Title: Blood and Blood Products ***Description:*** This effort develops and refines knowledge products (such as clinical practice guidelines, manuals, protocols, studies, and media), materials, and systems for control of internal bleeding and mitigation of shock; minimizing the effects of traumatic blood loss; preserving, storing, and transporting blood and blood products. ***FY 2021 Plans:*** Synthetic Blood Replacement ($0.987M) ? Will study use of whole blood as treatment for acute traumatic coagulopathy (blood clotting disorder). Next Generation Human-Derived Blood Replacement ($3.949M) ? Will identify new efficacious preservative solutions for platelets and whole blood. ? Will begin study of cellular therapies for treatment of acute radiation sickness combined with traumatic injury. ***FY 2020 to FY 2021 Increase/Decrease Statement:*** This work continues under this same project from previous title "Damage Control Resuscitation." Funding increase a result of level of effort required.	-	-	4.969
Title: Severe Burns ***Description:*** This effort conducts research to enhance the ability to treat acute severe burns at or near the point of injury; protect burn wounds from further injury, infection and inflammation, especially when definitive surgical burn wound care is delayed or unavailable; and accelerate wound healing and return to combat duty. ***FY 2021 Plans:*** Rapid Burn Injury Treatment and Return to Duty Cap Set 1 ($2.272M) ? Will assess novel technologies to prevent burn progression in casualties treated in far forward environments. ? Will develop new severe burn animal models in which to assess new burn treatments along with technologies that quantify burn wound healing rate and measure effectiveness of treatment. Next Generation Rapid Burn Injury Treatment and Return to Duty Cap Set 2 ($0.568M)	-	-	2.883

Exhibit R-2A, RDT&E Project Justification: PB 2021 Army		Date: February 2020
Appropriation/Budget Activity 2040 / 2	**R-1 Program Element (Number/Name)** PE 0602787A / *Medical Technology*	**Project (Number/Name)** MM4 / *Cbt Casualty Care Applied Rsch Technology*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2019	FY 2020	FY 2021
? Will develop new treatment approaches to protect burn wounds, prevent infection and inflammation, accelerate healing and restore function. ***FY 2020 to FY 2021 Increase/Decrease Statement:*** Decrease due to realignment of previous Combat Trauma Therapies sub-research areas, with the exception of Severe Burns, to new Prolonged Care research area.			
Title: Tactical Combat Casualty Care ***Description:*** This effort refines diagnostic and therapeutic medical devices, drugs, and new clinical practices for hemorrhage control, resuscitation, stabilization, and preservation of vital organ function that can be immediately applied by combat medical personnel in the pre-hospital combat setting. ***FY 2021 Plans:*** Advanced Tactical Combat Casualty Stabilization System Cap Set 2 ($0.423M) ? Will examine therapeutic approaches to preserving kidney function following crush injuries. Tactical Combat Casualty Stabilization System Cap Set 1 ($1.690M) ? Will evaluate catheter-based techniques to control non-compressible hemorrhage. ? Will characterize new animal pain models. ***FY 2020 to FY 2021 Increase/Decrease Statement:*** In FY21, this work is a continuation of work done under the previous title, "Pre-Hospital Tactical Combat Casualty Care", under the same project. The funding increase is a result of project realignment.	-	-	2.153
Title: Brain Trauma ***Description:*** This effort supports refinement of drug (includes mature drug technologies and those that are FDA approved for other indications) and therapeutic strategies to manage brain injury resulting from battlefield trauma. ***FY 2021 Plans:*** Drugs to Prevent and Treat Brain Injury ($1.751M) ? Will perform applied research on nanoparticles to evaluate their use as a drug delivery vehicle. ? Will study therapies that enhance inherent brain healing abilities. ? Will evaluate nicotine as a potential neuroprotective drug. Advanced Medic Brain Injury Diagnostic and Treatment System ($0.438M)	-	-	2.233

Exhibit R-2A, RDT&E Project Justification: PB 2021 Army		Date: February 2020
Appropriation/Budget Activity 2040 / 2	**R-1 Program Element (Number/Name)** PE 0602787A / *Medical Technology*	**Project (Number/Name)** MM4 / *Cbt Casualty Care Applied Rsch Technology*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2019	FY 2020	FY 2021
? Will study correlative relationships between brain injury-induced non-convulsive seizures, brain injury-specific biomarkers, and clinical outcomes. ***FY 2020 to FY 2021 Increase/Decrease Statement:*** Increase due to allocation of additional funds for study of novel drug delivery platforms.			
Title: FY 2020 SBIR/STTR Transfer ***Description:*** Funding transferred in accordance with Title 15 USC ?638 ***FY 2020 Plans:*** Funding transferred in accordance with Title 15 USC ?638 ***FY 2020 to FY 2021 Increase/Decrease Statement:*** Funding transferred in accordance with Title 15 USC ?638	-	0.222	-
Accomplishments/Planned Programs Subtotals	-	17.909	19.424

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2021 Army			Date: February 2020
Appropriation/Budget Activity 2040 / 2	R-1 Program Element (Number/Name) PE 0602787A / *Medical Technology*	Project (Number/Name) MM6 / *Medical Technologies to Support Dispersed Ops Tech*	

COST ($ in Millions)	Prior Years	FY 2019	FY 2020	FY 2021 Base	FY 2021 OCO	FY 2021 Total	FY 2022	FY 2023	FY 2024	FY 2025	Cost To Complete	Total Cost
MM6: *Medical Technologies to Support Dispersed Ops Tech*	-	0.000	12.109	14.417	-	14.417	12.940	14.257	14.016	13.001	0.000	80.740

Note

In Fiscal Year (FY) 2020, this Project is being realigned from:
Program element (PE) 0602787A Medical Technology
* Project XV5 Medical Capabilities to Support Dispersed Ops

A. Mission Description and Budget Item Justification

This Project supports two task areas: 1) Medical Robotic and Autonomous Systems (Med-RAS) focused on developing the ability to deliver emergency resupply of Medical material by ground or air, such as blood products, and, utilization of autonomous platforms to perform medical treatment and medical evacuations in dispersed and multi-domain battle environments. Enables teaming to deliver medical care, and establish medical performance criteria to ensure Soldiers have the physiological, cognitive, and psychological capacity to perform man-machine teaming; and, 2) Virtual Health to enable prolonged care and deciding faster by exploiting emerging communications and information technology for remote telemonitoring and telementoring between providers in Roles of Care 3 and 4 to patients in Roles of Care 1 and 2.

Promising work in this Project will be further matured in PE 0603002A (Medical Advanced Technology) / Project MM7 (Enabling Med Cap to Support Dispersed OPS Adv Tech).

The cited work is consistent with the Under Secretary of Defense for Research and Engineering priority focus areas and the Army Modernization Strategy.

Work in this Project is performed by the United States Army Medical Research and Development Command (USAMRDC), Fort Detrick, MD.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2019	FY 2020	FY 2021
Title: Medical Robotic and Autonomous Systems (Med-RAS)	-	7.852	9.904
Description: Research, design, and prototype autonomous and unmanned capabilities to deliver high quality combat casualty care in dispersed operations with limited or absent medical care personnel, and future medical robotic systems capable of providing autonomous combat casualty care while optimizing the medical logistic footprint in far-forward and dispersed geographic environments in support of the Army Multi-Domain Operations concept and the Army Force 2025 and Beyond vision. ***FY 2020 Plans:*** Will research the design of robotic systems, including physical interfaces and hardware configurations, to effectively implement and control resuscitation and critical care procedures driven by artificial intelligence (AI) and machine learning. Will explore			

Exhibit R-2A, RDT&E Project Justification: PB 2021 Army		Date: February 2020
Appropriation/Budget Activity 2040 / 2	**R-1 Program Element (Number/Name)** PE 0602787A / *Medical Technology*	**Project (Number/Name)** MM6 / *Medical Technologies to Support Dispersed Ops Tech*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2019	FY 2020	FY 2021
the feasibility of using robotic perception systems to detect and visualize combat casualties for autonomous treatment & extraction. Will research methods for integrating medical systems with emerging unmanned aerial system (UAS) platforms that address patient transport safety concerns, reliability of medical systems in flight, and low-bandwidth and cyber-secure transmission of medical data. Will design and prototype a medic?s AI assisted decision support system using lightweight ruggedized patient monitoring devices, hands-free input of medic observations, and approved joint tactical combat casualty/ prolonged field care guidelines as inputs to provide first responders at the point of injury with adaptive treatment and patient disposition recommendations in the absence of reach-back capabilities for remote telementoring. Will research and design autonomy-based countermeasures to signal latency and constrained bandwidth capabilities for conducting tele-robotic surgical tasks and procedures in low-comms environments.			
FY 2021 Plans: Medical Robotic and Autonomous Systems (Med-RAS) ($9.828M) ? Will design medical robotic systems, including physical interfaces and hardware configurations, for procedures driven by AI and Machine Learning (ML) by: 1) refining polytrauma protocols for animals, 2) conducting human stress testing in a Lower Body Negative Pressure (LBNP) chamber, and 3) performing lab testing of ?soft? robotic noninvasive sensing, force feedback control, needle insertion, patient immobilization, and airway access and insertion. ? Will expand methods for integrating medical systems with unmanned aerial system (UAS) platforms that address patient transport safety concerns, reliability of medical systems in flight, and low-bandwidth and cyber-secure transmission of medical data by 1) testing the patient simulator system on board a unmanned aerial vehicle (UAV) research platform and 2) prototyping and flight testing various communication architectures for closed-loop and tele-operated patient support systems. ? Will refine and further develop Prolonged Field Care guidelines for a prototype AI assisted Decision Support System (DSS). Based on previous year?s research, develop strategies to implement 1) predictive patient state algorithms, 2) ML capabilities to continually improve recommendations, and 3) automated patient encounter and medic interventions through speech to text technologies. ? Will expand research and design of autonomy-based countermeasures to signal latency and constrained bandwidth capabilities for conducting tele-robotic tasks by: 1) integrating force/torque sensing capabilities with the robotic vision system, and 2) designing semi-autonomous surgical protocols. ? Will design layout of a ?CASEVAC kit? subsystem of the Combat Medical Mission Module (CEMM) based on new en route care technologies to include: 1) remotely operated, or semi-autonomous/closed-loop intervention and patient management systems, and 2) enabling medical communications systems and telehealth/Virtual Health and 3) creating computer-aided design (CAD) models and constructing mock-up models.			
FY 2020 to FY 2021 Increase/Decrease Statement:			

Exhibit R-2A, RDT&E Project Justification: PB 2021 Army		Date: February 2020
Appropriation/Budget Activity 2040 / 2	**R-1 Program Element (Number/Name)** PE 0602787A / *Medical Technology*	**Project (Number/Name)** MM6 / *Medical Technologies to Support Dispersed Ops Tech*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2019	FY 2020	FY 2021
Funding increase due to additional MedRAS investments in autonomous casualty management, robotic perception for combat casualty care, and telesurgical robotic networks.			
Title: Virtual Health ***Description:*** Develop future Virtual Health enterprise process architectures and integrated physical solutions capable of supporting prolonged field care in conditions with limited or lacking traditional field communications. ***FY 2020 Plans:*** Will research and validate models of novel Virtual Health (VH) enterprise process architectures to provide new intersections of health information and knowledge far forward to support the Multi-Domain Operations. Will research and validate models for the Virtual Health support and integration with autonomous (real time) and/or semi-autonomous patient care capabilities. Will research and validate means to leverage contemporary VH data components to drive future semi-autonomous and autonomous VH system support tools. Will determine strategies for future linkages between the tactical environment and garrison based VH functions. Will determine novel strategies to identify VH consultants based on both availability and proximity to the VH needs. Will explore strategies for VH solutions that align with best practices to counteract threats from electronic warfare (EW). Will explore mechanisms to streamline the engagement with VH solutions by clinical end users in the operational environment. Will research and develop strategies and mechanisms to provide VH solutions when an established synchronous VH consultation is disrupted due to communication failure/outages to include, but not limited to, closed loop systems and machine learning techniques. ***FY 2021 Plans:*** Virtual Health Applications For Multi Domain Operational Environments ($4.438M) ? Will research and validate enterprise architectures for the Virtual Health support and integration with autonomous (real time) and/or semi-autonomous patient care capabilities. ? Will expand research and validate means to leverage contemporary VH data components to drive future semi-autonomous and autonomous VH system support tools. ? Will explore strategies for VH solutions that align with best practices to counteract threats from electronic warfare (EW). ? Will expand mechanisms to streamline the engagement with VH solutions by clinical end users in the operational environment. ? Will expand research mechanisms to provide VH solutions when an established synchronous VH consultation is disrupted due to communication failure/outages to include, but not limited to, closed loop systems and machine learning techniques. ***FY 2020 to FY 2021 Increase/Decrease Statement:*** Funding increase due to level of effort required.	-	3.894	4.513
Title: FY 2020 SBIR/STTR Transfer ***Description:*** Funding transferred in accordance with Title 15 USC ?638	-	0.363	-

Exhibit R-2A, RDT&E Project Justification: PB 2021 Army		Date: February 2020
Appropriation/Budget Activity 2040 / 2	**R-1 Program Element (Number/Name)** PE 0602787A / *Medical Technology*	**Project (Number/Name)** MM6 / *Medical Technologies to Support Dispersed Ops Tech*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2019	FY 2020	FY 2021
FY 2020 Plans: Funding transferred in accordance with Title 15 USC ?638 ***FY 2020 to FY 2021 Increase/Decrease Statement:*** Funding transferred in accordance with Title 15 USC ?638			
Accomplishments/Planned Programs Subtotals	-	12.109	14.417

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2021 Army			Date: February 2020
Appropriation/Budget Activity 2040 / 2	R-1 Program Element (Number/Name) PE 0602787A / *Medical Technology*	Project (Number/Name) MM8 / *Infectious Diseases and Applied Rsch Technology*	

COST ($ in Millions)	Prior Years	FY 2019	FY 2020	FY 2021 Base	FY 2021 OCO	FY 2021 Total	FY 2022	FY 2023	FY 2024	FY 2025	Cost To Complete	Total Cost
MM8: *Infectious Diseases and Applied Rsch Technology*	-	0.000	21.661	24.851	-	24.851	25.459	25.021	24.603	24.610	0.000	146.205

Note

In Fiscal Year (FY) 2020, this Project is being realigned from:
Program Element (PE) 0602787A Medical Technology
* Project 870 DoD Med Def Ag Inf Dis

A. Mission Description and Budget Item Justification

This Project conducts applied (pre-clinical) research for medical countermeasures to prevent naturally occurring infectious diseases that impact operational readiness. The Project builds on basic research to optimize lead countermeasures and determines their safety and efficacy in animal models of infection. Effective preventive countermeasures protect the Warfighter from disease and sustain readiness and operations. Infectious disease threats from parasitic diseases, bacterial diseases, and viral diseases are high priorities for military operations.

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

(1) Parasitic Diseases
(2) Bacterial Diseases
(3) Viral Diseases

The cited work is consistent with the Under Secretary of Defense (Research and Engineering) science and technology focus areas and the Army Modernization Strategy.

Work is managed by the United States Army Medical Research and Development Command (USAMRDC) 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.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2019	FY 2020	FY 2021
Title: Applied research on drugs and vaccines against parasitic diseases	-	9.981	13.706
Description: Develop and validate malaria preclinical animal models. Demonstrate and optimize prophylactic safety and efficacy in validated malaria preclinical animal models. Down-select lead malaria prophylactic candidates for use in human clinical trials.			
FY 2020 Plans:			

Exhibit R-2A, RDT&E Project Justification: PB 2021 Army		Date: February 2020
Appropriation/Budget Activity 2040 / 2	**R-1 Program Element (Number/Name)** PE 0602787A / *Medical Technology*	**Project (Number/Name)** MM8 / *Infectious Diseases and Applied Rsch Technology*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2019	FY 2020	FY 2021
Will complete studies in validated animal models to test reformulated triazine lead compound for safety and the dissemination in blood and tissues. These studies are required by the United States Food and Drug Administration (FDA) to enable oral dosing studies in humans. Will complete testing of pyrimidinylguanidine (a newly discovered family of similar chemical compounds that are active against malaria parasites in experimental animals) and primaquine-like compounds in primate malarias to enable initial human testing. Will complete laboratory based analyses of human immune cells and antibodies from Plasmodium falciparum malaria vaccine trials to enable down selection of a lead vaccine for transition to advanced development. Will conduct initial effectiveness trials of potential lead vaccine formulations in primate models of a relapsing malaria, Plasmodium vivax. ***FY 2021 Plans:*** Prevention and Treatment of Parasitic Diseases ($13.621M) ? Will perform test tube and/or cell-based studies to optimize and select the next lead prophylactic and/or treatment candidate for prevention and treatment of malaria. ? Will develop, assess and validate performance parameters of a mouse and/or non-human primate malaria efficacy models. ? Will evaluate the safety and efficacy of lead candidates in validated malaria animal models. ? Will assess technologies for extended release that provides long-term prophylaxis. ***FY 2020 to FY 2021 Increase/Decrease Statement:*** Funding change reflects planned lifecycle of this effort.			
Title: Applied Research to Prevent Viral Diseases ***Description:*** Develop and validate viral disease preclinical animal models. Demonstrate and optimize prophylactic safety and effectiveness in validated viral disease preclinical animal models. Down-select lead viral disease prophylactic candidates for use in human clinical trials. ***FY 2020 Plans:*** Will continue to sustain field sites as part of ongoing research partner efforts in testing dengue vaccine immunogenicity (ability to provoke an immune response) and effectiveness. Will continue to conduct immune cell and antibody assessments in human subjects exposed to dengue by dengue human infection model. Will continue to conduct immune cell and antibody assessments in human subjects immunized with purified inactivated virus and live attenuated virus vaccines. Will continue to explore multi-agent (combination of two or more molecules capable of inducing an immune response) vaccine concepts e.g., pan-hantavirus vaccine, Rift Valley fever, and Crimean Congo hemorrhagic fever vaccine. ***FY 2021 Plans:*** Prevention and Treatment of Viral Diseases ($5.986M) ? Will perform test tube and/or cell-based studies to optimize and select the next lead prophylactic and/or treatment candidate for prevention and treatment of viral diseases.	-	5.525	6.072

Exhibit R-2A, RDT&E Project Justification: PB 2021 Army		Date: February 2020
Appropriation/Budget Activity 2040 / 2	**R-1 Program Element (Number/Name)** PE 0602787A / *Medical Technology*	**Project (Number/Name)** MM8 / *Infectious Diseases and Applied Rsch Technology*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2019	FY 2020	FY 2021
? Will develop, assess and validate performance parameters of animal efficacy models of viral diseases. ? Will evaluate the safety and efficacy of lead candidates in validated viral diseases animal models. ? Will assess technologies for extended release that provides long-term prophylaxis. ***FY 2020 to FY 2021 Increase/Decrease Statement:*** Increase in funding reflecting level of effort required.			
Title: Applied Research to Prevent Bacterial Diseases ***Description:*** Optimize antigens and platforms for use in animal studies. Evaluate bacterial diarrheal vaccine candidates for safety, effectveness, and immunogenicity in animal models to advance to human clinical trials (ETEC, Shigella and Campylobacter). Examine host/pathogen/vector interactions for scrub typhus and other Rickettsial diseases. ***FY 2020 Plans:*** Will continue to develop and advance existing vaccine candidates against ETEC, Shigella and Campylobacter. Will continue to down select vaccine candidates for testing in animal models of diarrhea caused by ETEC, Shigella and Campylobacter. Will perform an assessment of multivalent (different types) vaccine candidates for ETEC, Shigella and Campylobacter in animal models of diarrhea. Will produce vaccine candidates for testing in humans using Good Manufacturing Processes. Will continue to evaluate the feasibility of clinical field sites for the assessment of vaccine candidates in humans. Will continue to maintain DoD subject matter expertise and laboratory capability in Rickettsiology to effectively detect, diagnose and treat rickettsial disease. ***FY 2021 Plans:*** Prevention and Treatment of Bacterial Diseases ($4.986M) ? Will perform test tube and/or cell-based studies to optimize and select the next lead prophylactic and/or treatment candidate for prevention and treatment of bacterial diarrheal disease. ? Will develop, assess and validate performance parameters of animal efficacy models of bacterial diarrheal and rickettsial diseases. ? Will evaluate the safety and efficacy of lead candidates in validated diarrheal disease animal models. ? Will assess technologies for extended release that provides long-term prophylaxis. ***FY 2020 to FY 2021 Increase/Decrease Statement:*** Decrease in funding reflecting level of effort required.	-	5.731	5.073
Title: FY 2020 SBIR/STTR Transfer ***Description:*** Funding transferred in accordance with Title 15 USC ?638 ***FY 2020 Plans:***	-	0.424	-

Exhibit R-2A, RDT&E Project Justification: PB 2021 Army		Date: February 2020
Appropriation/Budget Activity 2040 / 2	**R-1 Program Element (Number/Name)** PE 0602787A / *Medical Technology*	**Project (Number/Name)** MM8 / *Infectious Diseases and Applied Rsch Technology*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2019	FY 2020	FY 2021
Funding transferred in accordance with Title 15 USC ?638 ***FY 2020 to FY 2021 Increase/Decrease Statement:*** Funding transferred in accordance with Title 15 USC ?638			
Accomplishments/Planned Programs Subtotals	-	21.661	24.851

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2021 Army			Date: February 2020
Appropriation/Budget Activity 2040 / 2	R-1 Program Element (Number/Name) PE 0602787A / *Medical Technology*	Project (Number/Name) MN1 / *Applied Sensory Systems Trauma Technology*	

COST ($ in Millions)	Prior Years	FY 2019	FY 2020	FY 2021 Base	FY 2021 OCO	FY 2021 Total	FY 2022	FY 2023	FY 2024	FY 2025	Cost To Complete	Total Cost
MN1: *Applied Sensory Systems Trauma Technology*	-	0.000	7.615	6.961	-	6.961	6.169	3.092	3.144	3.044	0.000	30.025

Note

In Fiscal Year (FY) 2020, this Project is being realigned from: Program Element (PE) 0602787A Medical Technology
* Project ET4 Appl Resch in Clinical and Rehabilitative Medicine

A. Mission Description and Budget Item Justification

This Project conducts laboratory and animal studies for the purpose of developing novel, non-opioid drugs to treat pain in the austere battlefield environment with minimal side effects. Research to understand the influence of stress on the effectiveness of pain relief drugs (analgesics). All drugs, biological products, and medical devices are refined in accordance with Food and Drug Administration (FDA) regulations, which govern testing in animals to assess safety, toxicity, and effectiveness and subsequent human subject clinical trials.

Promising efforts identified in this Project are further matured under PE 0603002A (Medical Advanced Technology) / Project MN7 (Musculoskeletal Injury Screening Tool Advanced Technology).

The cited work is consistent with the Under 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 Medical Research and Development Command (USAMRDC), Fort Detrick, MD.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2019	FY 2020	FY 2021
Title: Applied Sensory Systems Trauma Technology	-	7.269	6.961
Description: This effort performs applied research in laboratory and animal studies to develop novel, non-opioid drugs to treat pain in the austere battlefield environment with minimal side effects.			
FY 2020 Plans: Will conduct preclinical testing to identify new targets (including peripheral ion channels) and to explore the potential of novel non-opioid drugs for improved pain management strategies. Also will investigate medical countermeasures to directed energy exposures.			
FY 2021 Plans: Applied Sensory Systems Trauma Technology ($3.967M)			

Exhibit R-2A, RDT&E Project Justification: PB 2021 Army		Date: February 2020
Appropriation/Budget Activity 2040 / 2	**R-1 Program Element (Number/Name)** PE 0602787A / *Medical Technology*	**Project (Number/Name)** MN1 / *Applied Sensory Systems Trauma Technology*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2019	FY 2020	FY 2021
? Will conduct preclinical evaluation of promising non-opioid, side effect-free analgesics in treating post-traumatic, moderate-to-severe pain. These drugs will act on non-opioid targets in the nervous system that inhibit pain signaling without affecting cognitive capability. Applied Sensory Systems Trauma Technology ($3.000M) ? Will identify and assess treatment for unconventionally-acquired brain injury (UBI) threat technologies ? Will conduct UBI human-like animal assessments ? Will validate UBI threat source symptomology and assess injury mechanisms ? Will transition understanding of injury mechanisms to enable direct medical diagnosis, treatment and clinical management. ***FY 2020 to FY 2021 Increase/Decrease Statement:*** Funding decrease based on level of effort required.			
Title: FY 2020 SBIR/STTR Transfer ***Description:*** Funding transferred in accordance with Title 15 USC ?638 ***FY 2020 Plans:*** Funding transferred in accordance with Title 15 USC ?638 ***FY 2020 to FY 2021 Increase/Decrease Statement:*** Funding transferred in accordance with Title 15 USC ?638	-	0.346	-
Accomplishments/Planned Programs Subtotals	-	7.615	6.961

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2021 Army			Date: February 2020
Appropriation/Budget Activity 2040 / 2	R-1 Program Element (Number/Name) PE 0602787A / *Medical Technology*	Project (Number/Name) VB3 / *MEDICAL TECHNOLOGY INITIATIVES (CA)*	

COST ($ in Millions)	Prior Years	FY 2019	FY 2020	FY 2021 Base	FY 2021 OCO	FY 2021 Total	FY 2022	FY 2023	FY 2024	FY 2025	Cost To Complete	Total Cost
VB3: *MEDICAL TECHNOLOGY INITIATIVES (CA)*	-	2.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	2.000

Note

Congressional increase for Peer-Reviewed Neurotoxin Exposure Treatment Parkinson's Research Program

A. Mission Description and Budget Item Justification

Congressional Interest Item funding for Neurotoxin Exposure Treatment.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2019	FY 2020
Congressional Add: Peer-Reviewed Neurotoxin Exposure Treatment Parkinson?s Research Program	2.000	-
FY 2019 Accomplishments: Peer-Reviewed Neurotoxin Exposure Treatment Parkinson?s Research Program		
Congressional Adds Subtotals	2.000	-

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2021 Army			Date: February 2020
Appropriation/Budget Activity 2040 / 2	R-1 Program Element (Number/Name) PE 0602787A / *Medical Technology*	Project (Number/Name) VB4 / *System Biology And Network Science Technology*	

COST ($ in Millions)	Prior Years	FY 2019	FY 2020	FY 2021 Base	FY 2021 OCO	FY 2021 Total	FY 2022	FY 2023	FY 2024	FY 2025	Cost To Complete	Total Cost
VB4: *System Biology And Network Science Technology*	-	1.383	0.600	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	1.983

Note

In Fiscal Year 2021 (FY21) this Project is Eliminated.

A. Mission Description and Budget Item Justification

This Project supports biological and clinical applied research using the data analysis and integration grid (Sys Bio Cube) as an overarching means of complex data usage to solve critical health problems. The primary capability of systems biology (field of study that focuses on complex interactions within biological systems, using a holistic approach) is the integration and analysis of complex human and animal study data and development of computational disease models, using global multi-omic methods to identify and discriminate unique combinations of biological molecules corresponding to clinical conditions (physiologic, immunologic, endocrine, etc.), supporting transition of research to clinical applications. This capability applies a systematic integrated approach to trace progression of illnesses and diseases and has already shown that the approach significantly reduces time, funds and effort invested in medical product development and refinement.

The cited work is consistent with the Under 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 Medical Research and Development Command (USAMRDC), Fort Detrick, MD.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2019	FY 2020	FY 2021
Title: Systems Biology	1.383	0.573	-
Description: The core capability for multidisciplinary applied research in systems biology enables integration and analysis of complex data from human and animal studies and development of computational network models, allowing researchers to differentiate among molecular signatures (unique combinations of biological molecules corresponding to clinical conditions) of disease, and supports transition of research to clinical applications for diseases of military relevance. Applied research is being conducted to identify biological networks that are causative of illness in Post-traumatic stress disorder (PTSD) and co-morbidities (presence of one or more diseases or disorders), coagulopathy (impaired ability to clot blood) of trauma, traumatic brain injury, pain, suicide, infectious disease, and immune responses. In particular, the studies of PTSD are directed to refine biomarkers for screening, early diagnosis and therapeutic target discovery.			
FY 2020 Plans:			

Exhibit R-2A, RDT&E Project Justification: PB 2021 Army		Date: February 2020
Appropriation/Budget Activity 2040 / 2	**R-1 Program Element (Number/Name)** PE 0602787A / *Medical Technology*	**Project (Number/Name)** VB4 / *System Biology And Network Science Technology*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2019	FY 2020	FY 2021
Will complete all studies under this effort. ***FY 2020 to FY 2021 Increase/Decrease Statement:*** Funding change reflects planned lifecycle of this effort			
Title: FY 2020 SBIR/STTR Transfer ***Description:*** Funding transferred in accordance with Title 15 USC ?638 ***FY 2020 Plans:*** Funding transferred in accordance with Title 15 USC ?638 ***FY 2020 to FY 2021 Increase/Decrease Statement:*** Funding transferred in accordance with Title 15 USC ?638	-	0.027	-
Accomplishments/Planned Programs Subtotals	1.383	0.600	-

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2021 Army			Date: February 2020
Appropriation/Budget Activity 2040 / 2	R-1 Program Element (Number/Name) PE 0602787A / *Medical Technology*	Project (Number/Name) XV5 / *Medical Capabilities to Support Dispersed Ops*	

COST ($ in Millions)	Prior Years	FY 2019	FY 2020	FY 2021 Base	FY 2021 OCO	FY 2021 Total	FY 2022	FY 2023	FY 2024	FY 2025	Cost To Complete	Total Cost
XV5: *Medical Capabilities to Support Dispersed Ops*	-	5.504	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	5.504

Note

In Fiscal Year (FY) 2020, this Project is being realigned to:
Program Element (PE) 0602787A Medical Technology
* Project MM6 Medical Technologies to Support Dispersed Ops Tech

A. Mission Description and Budget Item Justification

This project will design, develop, and improve medical robotic and autonomous systems (Med-RAS), Virtual Health for telemedicine and remotely delivered patient care, and unmanned capabilities of providing or supporting combat casualty care in far-forward and dispersed geographic environments. This research includes the design of semi-autonomous and closed-loop combat casualty triage, diagnosis, physiological monitoring, therapeutic intervention, casualty evacuation, telemedicine/ tele-mentoring and emergency medical resupply technologies for integration with emerging multi-purpose Army Robotics and Autonomous Systems (RAS) and Virtual Health/Telemedicine delivery platforms while optimizing the medical logistic footprint.

Promising work in this Project will be further matured in PE 0603002A (Medical Advanced Technology) / Project MM7 (Enabling Med Cap to Support Dispersed OPS Adv Tech).

The cited work is consistent with the Under Secretary of Defense for Research and Engineering priority focus areas and the Army Modernization Strategy.

Work in this Project is performed by the United States Army Medical Research and Development Command (USAMRDC), Fort Detrick, MD.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2019	FY 2020	FY 2021
Title: Medical Robotic and Autonomous Systems (Med-RAS) ***Description:*** Research, design, and prototype autonomous and unmanned capabilities to deliver high quality combat casualty care in dispersed operations with limited or absent medical care personnel in support of the Army Multi-Domain Operations concept and the Army Force 2025 and Beyond vision.	1.648	-	-
Title: Virtual Health ***Description:*** To develop future virtual health enterprise process architectures and integrated physical solutions capable of supporting prolonged field care in conditions with limited or lacking traditional field communications.	1.928	-	-
Title: Medical Aspects of Man-Machine Teamining/Medical Robotics	1.928	-	-

Exhibit R-2A, RDT&E Project Justification: PB 2021 Army		Date: February 2020
Appropriation/Budget Activity 2040 / 2	**R-1 Program Element (Number/Name)** PE 0602787A / *Medical Technology*	**Project (Number/Name)** XV5 / *Medical Capabilities to Support Dispersed Ops*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2019	FY 2020	FY 2021
Description: Researched and modeled virtual health enterprise process architectures to provide new intersections of health information and knowledge far forward to support multi-domain operations. Analyzed mechanisms for virtual health secure data transmission and communications in the tactical environment to facilitate use in very limited communication scenarios. Determined key physiological constructs that are predictive of health status and readiness for development of micro-footprint biosensor-based assessment tools.			
Accomplishments/Planned Programs Subtotals	5.504	-	-

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A