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Exhibit R-2, RDT&E Budget Item Justification: PB 2020 Army										Date: March 2019		
Appropriation/Budget Activity 2040: Research, Development, Test & Evaluation, Army / BA 3: Advanced Technology Development (ATD)					R-1 Program Element (Number/Name) PE 0603002A / Medical Advanced Technology							
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
Total Program Element	-	103.908	101.442	42.030	-	42.030	47.041	50.706	52.191	51.045	0.000	448.363
810: Ind Base Id Vacc&Drug	-	17.476	16.774	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	34.250
814: NEUROFIBROMATOSIS (CA)	-	15.000	15.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	30.000
840: Combat Injury Mgmt	-	17.755	19.770	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	37.525
945: BREAST CANCER STAMP PROCEEDS	-	0.554	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	0.554
97T: NEUROTOXIN EXPOSURE TREATMENT (CA)	-	16.000	16.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	32.000
ET5: Adv Tech Dev in Clinical & Rehabilitative Medicine	-	9.560	9.004	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	18.564
MG4: Tech Base/Enabling Res in Mil Occup Med Adv Tech	-	0.000	0.000	8.144	-	8.144	7.957	5.502	7.241	6.564	0.000	35.408
MM2: MEDICAL ADVANCE TECHNOLOGY INITIATIVES (CA)	-	8.000	8.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	16.000
MM3: Warfighter Medical Protection & Performance	-	19.563	16.894	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	36.457
MM5: Tech Base/Enabling Res Combat Cas Care Adv Tech	-	0.000	0.000	2.408	-	2.408	2.795	3.249	3.651	6.914	0.000	19.017
MM7: Enabling Med Cap to Support Dispersed OPS Adv Tech	-	0.000	0.000	1.819	-	1.819	3.851	4.826	4.778	5.000	0.000	20.274
MM9: Tech Base/Enabling Rsrch for Infect Dis Adv Tech	-	0.000	0.000	2.976	-	2.976	2.979	4.376	7.607	7.488	0.000	25.426
MN3: Immediate Cardiopulmonary Stabilization Adv Tech	-	0.000	0.000	1.903	-	1.903	1.894	1.808	1.895	1.940	0.000	9.440

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MN4: Advanced Life Support Advanced Technology	-	0.000	0.000	3.801	-	3.801	3.397	4.531	5.109	5.185	0.000	22.023	
MN5: Next Generation Blood Products Advanced Technology	-	0.000	0.000	5.964	-	5.964	6.634	6.752	6.972	7.056	0.000	33.378	
MN6: Blast & Head Impact Exposure Monitor Advanced Tech	-	0.000	0.000	1.412	-	1.412	1.412	1.412	0.000	0.000	0.000	4.236	
MN7: Musculoskeletal Injury Screening Tool Adv Tech	-	0.000	0.000	0.300	-	0.300	0.300	0.300	0.300	0.297	0.000	1.497	
MN8: Drugs to Prevent and Treat Malaria Advanced Tech	-	0.000	0.000	2.146	-	2.146	3.015	2.995	0.000	0.000	0.000	8.156	
MN9: Far Forward Behavioral Health Care Advanced Tech	-	0.000	0.000	0.266	-	0.266	0.272	0.278	0.285	0.000	0.000	1.101	
MO2: Traumatic Brain Injury (TBI) Treatment Adv Tech	-	0.000	0.000	4.285	-	4.285	4.406	4.387	4.083	0.797	0.000	17.958	
MO3: Military Occupational Fitness Standards Adv Tech	-	0.000	0.000	0.250	-	0.250	0.300	0.300	0.150	0.000	0.000	1.000	
MO4: Burn Recovery Optimization Advanced Technology	-	0.000	0.000	2.084	-	2.084	3.297	5.500	5.434	5.099	0.000	21.414	
MO7: Improved Bone Repair Advanced Technology	-	0.000	0.000	1.539	-	1.539	1.369	1.230	1.303	1.344	0.000	6.785	
MO8: Expeditionary Performance Nutrition Advanced Techn	-	0.000	0.000	0.200	-	0.200	0.429	0.511	0.520	0.476	0.000	2.136	
MO9: Vaccines to Prevent Dengue Fever Advanced Tech	-	0.000	0.000	2.533	-	2.533	2.434	2.399	2.713	2.736	0.000	12.815	
MP3: Phys Chem Toxicity Assessment Sys Adv Tech*	-	0.000	0.000	0.000	-	0.000	0.300	0.350	0.150	0.149	0.000	0.949	
*This project's R-2a exhibit has been suppressed due to funding not beginning until after FY 2020													

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<b>Appropriation/Budget Activity</b> 2040: <i>Research, Development, Test &amp; Evaluation, Army / BA 3: Advanced Technology Development (ATD)</i>		<b>R-1 Program Element (Number/Name)</b> PE 0603002A / <i>Medical Advanced Technology</i>
<b>Note</b> Project MM7 (Enabling Med Cap to Support Dispersed OPS Adv Tech) is a new start for Fiscal Year (FY) 2020.  As detailed in each Project-level R-2A exhibit, all other Projects in this Program Element (PE) either re-organize activities that were previously funded within this same PE or transition successful Applied Research from PE 0602787A (Medical Technology).  <b>A. Mission Description and Budget Item Justification</b> This Program Element (PE) matures and demonstrates advanced medical technologies including drugs, vaccines, medical diagnostic devices, measures for identification and vector control, and developing medical practices and procedures to effectively protect and improve the survivability of United States Forces across the entire spectrum of military operations. Tri-Service coordination and cooperative efforts are focused in four principal medical areas: Combat Casualty Care, Military Operational Medicine, Militarily Relevant Infectious Diseases, and Clinical and Rehabilitative Medicine.  Promising medical technologies are refined and validated through extensive testing, which is conducted in compliance with Food and Drug Administration (FDA) regulations for human medical products, and EPA regulations for insect-control products that impact humans or the environment (e.g., repellents and insecticides). The FDA requires medical products to undergo extensive preclinical testing in animals and/or other models to obtain preliminary effectiveness and safety information before they can be tested in human clinical trials. Clinical trials are conducted stepwise: first to prove the product is safe in humans, second to demonstrate the desired effectiveness and optimal dosage (amount to be administered) in a small group human study, and third to demonstrate effectiveness in large, diverse human populations. Each successive phase includes larger numbers of human subjects and requires FDA cognizance prior to proceeding. Work conducted in this PE primarily focuses on late stages of technology maturation activities required to conduct safety and effectiveness clinical trials. Some high-risk technologies may require additional maturation with FDA guidance prior to initiating these clinical trials. Such things as proof of product stability and purity are necessary to meet FDA standards before entering later stages of testing and prior to transitioning into a formal acquisition program where large pivotal trials in diverse populations will be conducted for licensure. Activities in this PE may include completion of preclinical animal studies and small safety and effectiveness studies involving humans according to FDA and EPA requirements. Promising medical technologies that are not regulated by the FDA or EPA are modeled, prototyped, and tested in relevant environments.  Blast research and research into maturing field rations in this PE are fully coordinated with the US Army Natick Soldier Research, Development, and Engineering Center. This coordination enables improved body armor design and rations for Soldiers. Additionally, the activities funded in this PE are externally peer reviewed and fully coordinated with all Services as well as other agencies through the Joint Technology Coordinating Groups of the Armed Services Biomedical Research Evaluation and Management (ASBREM) Community of Interest (COI). The ASBREM COI, formed under the authority of the Assistant Secretary of Defense for Research and Engineering, serves to facilitate coordination and prevent unnecessary duplication of effort within the Department of Defense's biomedical research and development community, as well as its associated enabling research areas.  The cited work is consistent with the Under Secretary of Defense (Research and Engineering) Science and Technology (S&T) focus areas and the Army Modernization Strategy.  Work in this PE is performed by: the U.S. Army Medical Research Materiel Command (USAMRMC), Fort Detrick, MD.		

**UNCLASSIFIED**

Exhibit R-2, RDT&E Budget Item Justification: PB 2020 Army				Date: March 2019		
Appropriation/Budget Activity		R-1 Program Element (Number/Name)				
2040: Research, Development, Test & Evaluation, Army I BA 3: Advanced Technology Development (ATD)		PE 0603002A I Medical Advanced Technology				
B. Program Change Summary (\$ in Millions)		FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total
Previous President's Budget		67.780	62.496	59.386	-	59.386
Current President's Budget		103.908	101.442	42.030	-	42.030
Total Adjustments		36.128	38.946	-17.356	-	-17.356
• Congressional General Reductions		-0.040	-0.054			
• Congressional Directed Reductions		-	-			
• Congressional Rescissions		-	-			
• Congressional Adds		39.000	39.000			
• Congressional Directed Transfers		-	-			
• Reprogrammings		-0.859	-			
• SBIR/STTR Transfer		-1.973	-			
• Adjustments to Budget Years		-	-	-17.356	-	-17.356
<b>Congressional Add Details (\$ in Millions, and Includes General Reductions)</b>						
<b>Project: 814: NEUROFIBROMATOSIS (CA)</b>						
Congressional Add: Peer-reviewed Neurofibromatosis Research						
Congressional Add Subtotals for Project: 814						

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Army										Date: March 2019		
Appropriation/Budget Activity 2040 / 3					R-1 Program Element (Number/Name) PE 0603002A / Medical Advanced Technology				Project (Number/Name) 810 / Ind Base Id Vacc&Drug			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
810: Ind Base Id Vacc&Drug	-	17.476	16.774	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	34.250

## Note

In Fiscal Year (FY) 2020 this Project is being realigned to the following Projects within this Program Element (PE):

- \* MM9 Tech Base/Enabling Research for Infectious Diseases Advanced Technology
- \* MO1 Vaccines to Prevent Hantavirus Associated Disease Advanced Technology
- \* MN8 Drugs to Prevent and Treat Malaria Advanced Technology
- \* MO5 Vaccine to Prevent P. falciparum Malaria Advanced Technology
- \* MO6 Vaccines to Prevent Bacterial Diarrheal Diseases Advanced Technology
- \* MO9 Vaccines to Prevent Dengue fever Advanced Technology

## A. Mission Description and Budget Item Justification

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

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

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

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

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Appropriation/Budget Activity 2040 / 3	R-1 Program Element (Number/Name) PE 0603002A / Medical Advanced Technology	Project (Number/Name) 810 / Ind Base Id Vacc&Drug		
Work is managed by the U.S. Army Medical Research and Materiel Command (USAMRMC) in coordination with the Naval Medical Research Center (NMRC). The Army is responsible for programming and funding all Department of Defense (DoD) naturally occurring infectious disease research requirements, thereby precluding duplication of effort within the Military Departments.				
Promising medical countermeasures identified in this Project are further matured under PE 0603807A (Medical Systems - Adv Dev), Project 808 (DoD Drug & Vacc Ad).				
The cited work is consistent with the Under Secretary of Defense (Research and Engineering) Science and Technology (S&T) focus areas and the Army Modernization Strategy. All FY20 adjustments align program resources to Army Modernization Priorities in support of the National Defense Strategy.				
Work in this Project is performed by USAMRMC at Fort Detrick, MD.				
Efforts in this Project support the Soldier portfolio and the principal area of Military Relevant Infectious Diseases.				
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2018	FY 2019	FY 2020
Title: Advanced Technology Research on drugs and vaccines against parasitic diseases		6.813	6.404	-
Description: This effort selects promising anti-parasitic drug candidates for treating malaria and leishmaniasis for testing in humans, and prepares data packages required for FDA approval of testing in humans. Studies have shown that the malaria parasite can become resistant to existing drugs, which makes it necessary to continually develop new and more effective and safe treatments. This effort selects candidate vaccines for various types of malaria, including the severe form of malaria (Plasmodium falciparum) and the less severe but relapsing form (Plasmodium vivax), prepares technical data packages required for FDA approval of testing in humans, and conducts testing of promising malaria vaccine candidates in humans. A malaria vaccine would minimize the progression and impact of drug resistance and eliminate the need to take preventive anti-malarial drugs.				
FY 2019 Plans:				
Initiate safety and analytic studies to assess natural break-down of candidate drugs within the human body to improve drug safety and effectiveness for treatment and prevention of malaria for selected triazine lead compound. Complete laboratory clinical trials to assess performance of lead Plasmodium falciparum malaria vaccine candidates. These activities enable down-selection of a lead vaccine for transition to advanced development. Validate laboratory-based immune measures of protection and correlate with protective effectiveness among candidate vaccines undergoing clinical trials.				
FY 2019 to FY 2020 Increase/Decrease Statement:				
In FY 2020 funds have been realigned within this PE to Projects MM9, MN8 and MO5				
Title: Bacterial Disease Threats		4.188	3.859	-

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Appropriation/Budget Activity 2040 / 3	R-1 Program Element (Number/Name) PE 0603002A / Medical Advanced Technology	Project (Number/Name) 810 / Ind Base Id Vacc&Drug		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2018	FY 2019	FY 2020
<p><b>Description:</b> This effort selects promising candidate vaccines against each of the three main bacterial causes of diarrhea (E. coli, Campylobacter, and Shigella) that pose significant threat during initial deployments, for testing in human subjects. Data packages are prepared, as required for FDA approval, and testing is conducted in human subjects.</p> <p><b>FY 2019 Plans:</b> Continue to develop and advance multiple vaccine candidates for Shigella, ETEC and Campylobacter. Prepare data packages for the FDA to test suitable vaccine candidates in humans for safety and effectiveness. Test the vaccine candidates in human clinical trials for safety and effectiveness for Shigella, ETEC and Campylobacter.</p> <p><b>FY 2019 to FY 2020 Increase/Decrease Statement:</b> In FY 2020 funds have been realigned within this PE to Projects MM9 and MO6</p>				
<p><b>Title:</b> Viral Disease Threats</p> <p><b>Description:</b> This effort progresses the most promising vaccine candidates against dengue fever (a severe debilitating disease caused by a virus and transmitted by a mosquito) and hantavirus (severe viral infection that causes internal bleeding and is contracted from close contact with rodents), conducts FDA-required nonclinical safety and protection testing (laboratory- based) in animals, prepares FDA investigational new drug technical data packages, and conducts clinical testing of candidate vaccines in humans.</p> <p><b>FY 2019 Plans:</b> Continue to evaluate safety and initial effectiveness of commercial partner dengue vaccine candidates undergoing testing in South East Asia and Latin America. Complete vaccine immunogenicity (ability to provoke an immune response) testing followed by dengue human infection model challenge and effectiveness testing of human subjects immunized with combination inactivated and weakened forms of virus vaccines. Engage commercial partner to pursue development of purified inactivated dengue virus vaccine alone or in combination with live attenuated product. Pursue an expanded Hemorrhagic Fever with Renal Syndrome DNA vaccine clinical trial in a country that has endemic HFRS cases. Test for safety and effectiveness of the HFRS DNA vaccine.</p> <p><b>FY 2019 to FY 2020 Increase/Decrease Statement:</b> In FY 2020 funds have been realigned within this PE to Projects MM9, MO1, and MO9</p>		4.897	5.493	-
<p><b>Title:</b> Diagnostics and Disease Transmission Control</p> <p><b>Description:</b> This effort conducts human subject testing of FDA-regulated field medical diagnostic devices and EPA-approved measures to control arthropod (i.e., insects, ticks &amp; mites) -borne pathogens (infectious agents) that cause diseases such as Q fever, Sand fly fever, and Japanese encephalitis.</p>		1.578	0.585	-

**UNCLASSIFIED**

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<b>Appropriation/Budget Activity</b> 2040 / 3	<b>R-1 Program Element (Number/Name)</b> PE 0603002A / <i>Medical Advanced Technology</i>	<b>Project (Number/Name)</b> 810 / <i>Ind Base Id Vacc&amp;Drug</i>	
<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>		<b>FY 2018</b>	<b>FY 2019</b>
<b><i>FY 2019 Plans:</i></b> Continue to improve data collection and characterization of arthropod vectors. Evaluate new dipsticks (pathogen detection lateral flow diagnostic devices). Continue to field test Ovitrap (mosquito detection/monitor device) and other vector control methods including repellants spatial devices.  <b><i>FY 2019 to FY 2020 Increase/Decrease Statement:</i></b> These research efforts end in FY 2019			
<b><i>Title:</i></b> FY 2019 SBIR / STTR Transfer  <b><i>FY 2019 Plans:</i></b> FY 2019 SBIR / STTR Transfer  <b><i>FY 2019 to FY 2020 Increase/Decrease Statement:</i></b> FY 2019 SBIR / STTR Transfer		-	0.433
<b>Accomplishments/Planned Programs Subtotals</b>		17.476	16.774
<b>C. Other Program Funding Summary (\$ in Millions)</b> N/A  <b>Remarks</b>  <b>D. Acquisition Strategy</b> N/A  <b>E. Performance Metrics</b> N/A			



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<b>Appropriation/Budget Activity</b> 2040 / 3					<b>R-1 Program Element (Number/Name)</b> PE 0603002A / <i>Medical Advanced Technology</i>				<b>Project (Number/Name)</b> 814 / <i>NEUROFIBROMATOSIS (CA)</i>																		
<b>COST (\$ in Millions)</b>	<b>Prior Years</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020 Base</b>	<b>FY 2020 OCO</b>	<b>FY 2020 Total</b>	<b>FY 2021</b>	<b>FY 2022</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>Cost To Complete</b>	<b>Total Cost</b>															
814: <i>NEUROFIBROMATOSIS (CA)</i>	-	15.000	15.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	30.000															
<p><b><u>Note</u></b> Congressional increase for Neurofibromatosis Research Program</p> <p><b><u>A. Mission Description and Budget Item Justification</u></b> Congressional Interest Item funding for Neurofibromatosis research.</p> <p><b><u>B. Accomplishments/Planned Programs (\$ in Millions)</u></b></p> <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td></td> <td align="center"><b>FY 2018</b></td> <td align="center"><b>FY 2019</b></td> </tr> <tr> <td><b><i>Congressional Add:</i></b> Peer-reviewed Neurofibromatosis Research</td> <td align="center">15.000</td> <td align="center">15.000</td> </tr> <tr> <td><b><i>FY 2018 Accomplishments:</i></b> Peer-reviewed Neurofibromatosis Research</td> <td></td> <td></td> </tr> <tr> <td><b><i>FY 2019 Plans:</i></b> Peer-reviewed Neurofibromatosis Research</td> <td></td> <td></td> </tr> <tr> <td align="right"><b>Congressional Adds Subtotals</b></td> <td align="center">15.000</td> <td align="center">15.000</td> </tr> </table> <p><b><u>C. Other Program Funding Summary (\$ in Millions)</u></b> N/A</p> <p><b><u>Remarks</u></b></p> <p><b><u>D. Acquisition Strategy</u></b> N/A</p> <p><b><u>E. Performance Metrics</u></b> N/A</p>														<b>FY 2018</b>	<b>FY 2019</b>	<b><i>Congressional Add:</i></b> Peer-reviewed Neurofibromatosis Research	15.000	15.000	<b><i>FY 2018 Accomplishments:</i></b> Peer-reviewed Neurofibromatosis Research			<b><i>FY 2019 Plans:</i></b> Peer-reviewed Neurofibromatosis Research			<b>Congressional Adds Subtotals</b>	15.000	15.000
	<b>FY 2018</b>	<b>FY 2019</b>																									
<b><i>Congressional Add:</i></b> Peer-reviewed Neurofibromatosis Research	15.000	15.000																									
<b><i>FY 2018 Accomplishments:</i></b> Peer-reviewed Neurofibromatosis Research																											
<b><i>FY 2019 Plans:</i></b> Peer-reviewed Neurofibromatosis Research																											
<b>Congressional Adds Subtotals</b>	15.000	15.000																									

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Appropriation/Budget Activity 2040 / 3					R-1 Program Element (Number/Name) PE 0603002A / Medical Advanced Technology				Project (Number/Name) 840 / Combat Injury Mgmt			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
840: Combat Injury Mgmt	-	17.755	19.770	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	37.525

## Note

In Fiscal Year (FY) 2020 this Project is realigned to:

Program Element (PE) 0603002A Medical Advanced Technology

- \* Project MM5 Tech Base/Enabling Research for Combat Casualty Care Advanced Technology
- \* Project MN3 Immediate Cardiopulmonary Stabilization Advanced Technology
- \* Project MN4 Advanced Life Support Advanced Technology
- \* Project MN5 Next Generation Blood Products Advanced Technology
- \* Project MO2 Traumatic Brain Injury (TBI) Treatment Advanced Technology
- \* Project MO4 Burn Recovery Optimization Advanced Technology
- \* Project MO7 Improved Bone Repair Advanced Technology

## A. Mission Description and Budget Item Justification

This Project matures, demonstrates, and validates promising medical technologies and new clinical practices for control of severe bleeding, treatment for traumatic brain injury (TBI), resuscitation and stabilization of trauma patients, acute treatment of extremity (arms and legs) and facial injuries, treatment of severe burn wounds, treatment of single and multiple organ failures due to trauma, and predictive indicators and decision aids for life support systems. Emphasis is placed on provision of prolonged field care when evacuation to theater hospitals is delayed.

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

- (1) Damage Control Resuscitation
- (2) Combat Trauma Therapies
- (3) Traumatic Brain Injury
- (4) Combat Critical Care Engineering

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

Promising efforts identified through Applied Research conducted under PE 0602787A, Project 874, are further matured under this Project. Promising results identified under this Project are further matured under PE 0603807A, Project 836.

The cited work is consistent with the Under Secretary of Defense (Research and Engineering) science and technology focus areas and the Army Modernization Strategy. All FY 2020 adjustments align program resources to Army Modernization Priorities in support of the National Defense Strategy.

# UNCLASSIFIED

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Appropriation/Budget Activity 2040 / 3	R-1 Program Element (Number/Name) PE 0603002A / Medical Advanced Technology	Project (Number/Name) 840 / Combat Injury Mgmt		
Work in this Project is performed by: the U.S. Army Medical Research Materiel Command (USAMRMC), Fort Detrick, MD..				
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2018	FY 2019	FY 2020
<p><b>Title:</b> Damage Control Resuscitation</p> <p><b>Description:</b> This effort supports work required to validate safety and effectiveness of drugs and medical procedures to control or stop bleeding, maintain metabolism (the chemical processes that are required to maintain life) minimize harmful inflammation after major trauma preserving tissue function, and prevent or minimize secondary organ failure (including brain and spinal cord injury).</p> <p><b>FY 2019 Plans:</b> Begin clinical trial to demonstrate safety of cold-stored platelets in human subjects. Evaluate stem cell safety and effectiveness in animal model of severe traumatic injury, bleeding, and inflammation. Assess current bleeding control products under prolonged care scenarios (i.e., when medical evacuation is delayed or prolonged). Perform preclinical studies to determine physiological effects of endovascular (refers to device that is directly introduced into a major blood vessel) bleeding control product use on subsequent fluid resuscitation effectiveness. Evaluate mechanical interventions for bleeding not controlled by application of pressure to determine best products and practices. Assess animal studies to determine effect of prolonged low blood pressure resuscitation on survival following definitive surgical repair and full resuscitation. Evaluate combinations of blood products and drugs to determine which optimally mitigate the effects of inflammation and prolonged ischemia (inadequate or absent blood supply) produced in critical tissues by traumatic bleeding. Continue evaluation of methods to refrigerate whole blood that do not impair platelet function.</p> <p><b>FY 2019 to FY 2020 Increase/Decrease Statement:</b> In FY 2020 funds have been realigned to the newly established 6.3 projects</p>		4.694	5.588	-
<p><b>Title:</b> Combat Trauma Therapies</p> <p><b>Description:</b> This effort focuses on work required to validate safety and effectiveness of drugs, biologics, and medical procedures intended to minimize immediate and long-term effects from battlefield injuries.</p> <p><b>FY 2019 Plans:</b> Assess path of healing in animal burn wounds and measure time to wound closure for various degrees of burn wounds. Continue retrospective analyses to identify clinical determinants of long-term disability in casualties with musculoskeletal injuries. Continue animal studies to determine optimal concentration of a commonly used antiseptic solution for initial wash-out of dismounted complex battlefield injuries. Continue studies in animals to evaluate effectiveness of products to combat wound infection, inflammation and scarring of delayed wound healing.</p> <p><b>FY 2019 to FY 2020 Increase/Decrease Statement:</b></p>		5.997	5.116	-

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2020 Army		<b>Date:</b> March 2019	
<b>Appropriation/Budget Activity</b> 2040 / 3	<b>R-1 Program Element (Number/Name)</b> PE 0603002A / <i>Medical Advanced Technology</i>	<b>Project (Number/Name)</b> 840 / <i>Combat Injury Mgmt</i>	
<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>		<b>FY 2018</b>	<b>FY 2019</b>
In FY 2020 funds have been realigned to the newly established 6.3 projects			<b>FY 2020</b>
<b>Title:</b> Traumatic Brain Injury (TBI) <b>Description:</b> This effort supports work required to validate safety and effectiveness of drugs, biologics, and medical procedures intended to minimize immediate and long-term effects from TBI. <b>FY 2019 Plans:</b> Validate novel biomarkers of TBI using human serum samples across the spectrum of TBI severity. Refine drugs and drug treatment protocols to optimize outcome during the subacute (first two to three weeks following injury) and chronic (one to three months following injury) TBI recovery time frames. <b>FY 2019 to FY 2020 Increase/Decrease Statement:</b> In FY 2020 funds have been realigned to the newly established 6.3 projects		3.948	3.948
<b>Title:</b> Combat Critical Care Engineering <b>Description:</b> This effort supports development of diagnostic and therapeutic medical devices, algorithms, software, and data-processing systems for resuscitation, stabilization and life support, and development of improved critical care nursing practices. The aim is to improve care of severely injured or ill casualties during transport and in theater hospitals, and to develop and evaluate technologies to treat vital organ failure caused by traumatic injury. <b>FY 2019 Plans:</b> Conduct safety/effectiveness study of miniaturized extracorporeal life support system in trauma burn patients with lung injury. Conduct large animal studies of an automated type of endovascular balloon occlusion of the aorta (used for control of intra-abdominal bleeding) to determine its safety and ability to prevent organ failure. Create evidence-based competency assessment program for combat casualty care skills for all provider levels. Create centralized support system that includes best practice guidelines for evidence-based trauma management throughout continuum of care and supports telemedicine. Evaluate performance of life-saving intervention prediction algorithm in intensive care environment. Measure the performance of the Burn Resuscitation Decision Support System (a device that guides fluid resuscitation in patients with severe burns) technology in civilian burn centers. Develop a model to predict wound closure rate and time to full closure in burn patients. <b>FY 2019 to FY 2020 Increase/Decrease Statement:</b> In FY 2020 funds have been realigned to the newly established 6.3 projects.		3.116	4.648
<b>Title:</b> FY 2019 SBIR / STTR Transfer <b>FY 2019 Plans:</b>		-	0.470
			-

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2020 Army		<b>Date:</b> March 2019	
<b>Appropriation/Budget Activity</b> 2040 / 3	<b>R-1 Program Element (Number/Name)</b> PE 0603002A / <i>Medical Advanced Technology</i>	<b>Project (Number/Name)</b> 840 / <i>Combat Injury Mgmt</i>	
<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>		<b>FY 2018</b>	<b>FY 2019</b>
FY 2019 SBIR / STTR Transfer			
<b><i>FY 2019 to FY 2020 Increase/Decrease Statement:</i></b> FY 2019 SBIR / STTR Transfer			
<b>Accomplishments/Planned Programs Subtotals</b>		17.755	19.770
<b>C. Other Program Funding Summary (\$ in Millions)</b> N/A			
<b>Remarks</b>			
<b>D. Acquisition Strategy</b> N/A			
<b>E. Performance Metrics</b> N/A			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Army										Date: March 2019		
Appropriation/Budget Activity 2040 / 3					R-1 Program Element (Number/Name) PE 0603002A / Medical Advanced Technology				Project (Number/Name) 945 / BREAST CANCER STAMP PROCEEDS			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
945: BREAST CANCER STAMP PROCEEDS	-	0.554	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	0.554
A. Mission Description and Budget Item Justification This Project receives funds as proceeds from the sale of Breast Cancer Stamps.												
B. Accomplishments/Planned Programs (\$ in Millions)									FY 2018	FY 2019	FY 2020	
Title: Breast Cancer Stamp Proceeds									0.554	-	-	
Accomplishments/Planned Programs Subtotals									0.554	-	-	
C. Other Program Funding Summary (\$ in Millions) N/A												
Remarks												
D. Acquisition Strategy N/A												
E. Performance Metrics N/A												

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2020 Army										<b>Date:</b> March 2019		
<b>Appropriation/Budget Activity</b> 2040 / 3					<b>R-1 Program Element (Number/Name)</b> PE 0603002A / <i>Medical Advanced Technology</i>				<b>Project (Number/Name)</b> 97T / <i>NEUROTOXIN EXPOSURE TREATMENT (CA)</i>			
<b>COST (\$ in Millions)</b>	<b>Prior Years</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020 Base</b>	<b>FY 2020 OCO</b>	<b>FY 2020 Total</b>	<b>FY 2021</b>	<b>FY 2022</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>Cost To Complete</b>	<b>Total Cost</b>
97T: <i>NEUROTOXIN EXPOSURE TREATMENT (CA)</i>	-	16.000	16.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	32.000

**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>B. Accomplishments/Planned Programs (\$ in Millions)</b>	<b>FY 2018</b>	<b>FY 2019</b>
<b>Congressional Add:</b> Peer-reviewed Neurotoxin Exposure Treatment Parkinson's Research	16.000	16.000
<b>FY 2018 Accomplishments:</b> Peer-reviewed Neurotoxin Exposure Treatment Parkinson's Research		
<b>FY 2019 Plans:</b> Peer-reviewed Neurotoxin Exposure Treatment Parkinson's Research		
<b>Congressional Adds Subtotals</b>	16.000	16.000

**C. Other Program Funding Summary (\$ in Millions)**  
N/A

**Remarks**

**D. Acquisition Strategy**  
N/A

**E. Performance Metrics**  
N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Army										Date: March 2019		
Appropriation/Budget Activity 2040 / 3					R-1 Program Element (Number/Name) PE 0603002A / Medical Advanced Technology				Project (Number/Name) ET5 / Adv Tech Dev in Clinical & Rehabilitative Medicine			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
ET5: Adv Tech Dev in Clinical & Rehabilitative Medicine	-	9.560	9.004	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	18.564
Note This Project ends in FY 2019.												
A. Mission Description and Budget Item Justification This Project supports basic research on experimental models that are developed to support in-depth trauma research studies. This Project includes studies to understand the healing of burned or traumatically injured tissues including eye, bone, nerve, skin, muscle, organs and composite tissues. Such efforts will minimize lost duty time and provide military medical capabilities for post-evacuation restorative and rehabilitative care.  Research conducted in this Project focuses on clinical and rehabilitative medicine.  Work in this Project complements and is fully coordinated with Program Element (PE) 0602787A (Medical 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 U.S. Army Medical Research Materiel Command (USAMRMC), Fort Detrick, MD.												
B. Accomplishments/Planned Programs (\$ in Millions)									FY 2018	FY 2019	FY 2020	
Title: Clinical and Rehabilitative Medicine									9.560	8.683	-	
Description: This effort supports clinical studies to advance treatment and restoration strategies of traumatically-injured tissues, to include skin, nerve, bone and ocular (eye) tissue to ultimately restore function and appearance. Areas of interest for regenerative medicine include healing without scarring, repair of compartment syndrome (muscle and nerve damage following reduced blood flow caused by swelling), replacement skin, facial reconstruction and vision restoration.												
FY 2019 Plans: Conduct advanced pre-clinical trials to ensure the safety and effectiveness of an ocular bandage designed to rescue vision post-injury. Continue pre-clinical investigation of engineered skin substitutes for regeneration of functional skin without scarring. Conduct pre-clinical trials of devices for repairing traumatic injury to craniofacial and extremity tissues. Evaluate candidate biological therapies and drugs for reduced need of immunosuppressive (inhibition of the immune response) therapies following												



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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2020 Army		<b>Date:</b> March 2019	
<b>Appropriation/Budget Activity</b> 2040 / 3	<b>R-1 Program Element (Number/Name)</b> PE 0603002A / <i>Medical Advanced Technology</i>	<b>Project (Number/Name)</b> ET5 / <i>Adv Tech Dev in Clinical &amp; Rehabilitative Medicine</i>	
<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>		<b>FY 2018</b>	<b>FY 2019</b>
hand and face transplants. Down-select identified candidate technologies and biologics that create a wound environment more conducive to bone healing.			
<b>FY 2019 to FY 2020 Increase/Decrease Statement:</b> In FY 2020 funds have been realigned to the newly established 6.3 projects MN2 and MP4			
<b>Title:</b> FY 2019 SBIR / STTR Transfer		-	0.321
<b>FY 2019 Plans:</b> FY 2019 SBIR / STTR Transfer			
<b>FY 2019 to FY 2020 Increase/Decrease Statement:</b> FY 2019 SBIR / STTR Transfer			
<b>Accomplishments/Planned Programs Subtotals</b>		9.560	9.004
<b>C. Other Program Funding Summary (\$ in Millions)</b> N/A			
<b>Remarks</b>			
<b>D. Acquisition Strategy</b> N/A			
<b>E. Performance Metrics</b> N/A			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Army										Date: March 2019		
Appropriation/Budget Activity 2040 / 3					R-1 Program Element (Number/Name) PE 0603002A / Medical Advanced Technology				Project (Number/Name) MG4 / Tech Base/Enabling Res in Mil Occup Med Adv Tech			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
MG4: Tech Base/Enabling Res in Mil Occup Med Adv Tech	-	0.000	0.000	8.144	-	8.144	7.957	5.502	7.241	6.564	0.000	35.408

## Note

In Fiscal Year (FY) 2020 this Project was realigned from:  
Program Element (PE) 0603002A Medical Advanced Technology  
\* Project MM3 Warfighter Medical Protection & Performance

## A. Mission Description and Budget Item Justification

Medical efforts support laboratory studies and field demonstrations of biomedical products designed to counteract diverse environmental, physiological and psychological stressors, as well as reduce the impacts of hazards encountered in training and operational environments. Initiatives will demonstrate and transition medical technologies to support Soldier/squad survivability under demanding operational tempo in order to protect, optimize and enhance Soldier performance & sustain lethality across the diverse range of military operations.

The four main thrust areas are:

- (1) Physiological Health,
- (2) Environmental Protection,
- (3) Injury Prevention and Reduction,
- (4) Psychological (mental) Health and Resilience.

The cited work is fully coordinated with Natick Soldier Research Development (NSRDEC), Natick, MA and with other Services in order to avoid duplication of effort.

The cited work is consistent with the Under Secretary of Defense (Research and Engineering) science and technology focus areas and the Army Modernization Strategy. All FY 2020 adjustments align program resources to Army Modernization Priorities in support of the National Defense Strategy.

Work in this Project is performed by: the U.S. Army Medical Research Materiel Command (USAMRMC), Fort Detrick, MD..

## B. Accomplishments/Planned Programs (\$ in Millions)

	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>
<b>Title:</b> Injury Prevention & Reduction	-	-	0.866
<b>Description:</b> This effort supports and validates injury prediction tools and return-to-duty assessments for brain, spine, and chest injury from blast, blunt, and ballistic impact. These are all priorities for Program Executive Office (PEO)-Soldier and support various Maneuver Center of Excellence programs to include: Soldier Protection Systems (e.g. Integrated Head Protection Systems and Vital Toro Protection Systems). This effort also addresses need for validated aeromedical standards and strategies			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Army		Date: March 2019		
Appropriation/Budget Activity 2040 / 3	R-1 Program Element (Number/Name) PE 0603002A / Medical Advanced Technology	Project (Number/Name) MG4 / Tech Base/Enabling Res in Mil Occup Med Adv Tech		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2018	FY 2019	FY 2020
to enable aircrew to effectively fight, navigate, and land under a range of degraded visual environments and provide aeromedical return to duty guidelines after neurosensory injury (deficits in the nervous system control of vision, hearing, taste, smell, and touch). This supports Cross Functional Team (CFT): Future Vertical Lift.				
<b>FY 2020 Plans:</b> Will continue to validate musculoskeletal injury risk models and return-to-duty criteria from data collected from training and theater. Will continue to validate cervical spine injury risk (Head Supported Mass Criteria) criteria that will inform acquisition of new head mounted technologies the Army CFTs are pursuing. Will validate health hazard and medical requirements that will inform Army Aviation fitness for duty and Future Vertical Lift requirements.				
<b>FY 2019 to FY 2020 Increase/Decrease Statement:</b> Ongoing work transferred from other project due to S&T Financial Restructuring. In FY 2020, funding for Injury Prevention and Reduction decreased due to: 1) eliminated funding for Sensory Performance, Injury & Protection in order to accelerate new priority programs within MRMC; and 2) reduced funding for Blunt, Blast & Accelerative Injury.				
<b>Title:</b> Physiological Health & Performance		-	-	2.546
<b>Description:</b> This effort supports and matures laboratory prototypes, evaluates nutritional formulations and interventions, and validates decision aids for the prediction of Soldier performance in high operational tempo military environments.				
<b>FY 2020 Plans:</b> Will evaluate impact of sleep on high operational tempo military performance. Will demonstrate the impact of sleep deprivation and caffeine on operationally relevant complex cognitive processes. Will validate time-restricted spectral analyses of standard polysomnography to predict future behavior and estimate previous sleep quality and quantity. Will evaluate low-current brain stimulation as a cognitive enhancer during periods of sleep loss. Will evaluate psychophysiological indicators of aviator flight performance under workload conditions. Will mature evidence-based algorithmic modelling of aircrew clinical risk. Will evaluate effects of refractive/corrective eye surgery and corneal aberration on contrast sensitivity and flight safety. Will validate dining satisfaction and quality surveys at military dining facilities.				
<b>FY 2019 to FY 2020 Increase/Decrease Statement:</b> Ongoing work realigned from other project due to S&T Financial Restructuring. In FY 2020, increased funding for Physiological Health & Performance is due to normal and planned progression of existing efforts in the high priority of program efforts in sleep, nutrition and human performance.				
<b>Title:</b> Psychological Health & Resilience		-	-	2.818
<b>Description:</b> This effort supports and validates neurocognitive (relating to or involving the central nervous system and cognitive abilities) assessment and brain injury detection methods, and validates tools and preclinical methods to treat post-traumatic				

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Army			Date: March 2019		
Appropriation/Budget Activity 2040 / 3		R-1 Program Element (Number/Name) PE 0603002A / Medical Advanced Technology		Project (Number/Name) MG4 / Tech Base/Enabling Res in Mil Occup Med Adv Tech	
<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>			<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>
<p>stress disorder in a military population. This effort also supports validation of interventions in Warfighters for post-traumatic stress disorder (PTSD), validation of biomarkers of individual PTSD symptoms, validation of methods to follow effectiveness of PTSD treatments, validation of neuroprotective (protection of nerves and nervous system) interventions and validation of strategies to prevent neurocognitive deficits (reduced ability to learn and comprehend) and symptomatology associated with brain injury. This effort matures and validates early interventions to prevent and reduce military stressor and 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 matures and validates tools and interventions to enhance and sustain psychological resilience throughout Soldiers' careers.</p> <p><b>FY 2020 Plans:</b> Will deliver a decision-making support tool to guide management of suicide-related events in garrison. Will conduct suicide prevention studies to evaluate effectiveness of Internet-delivered brief interventions to improve Service member mental health during transition periods. Will conduct studies to validate easy-to-use evidence-based interventions to improve behavioral health in units by leveraging individual, team and leader-specific behaviors at platoon and company levels. Will evaluate optimally tailored resilience training paradigm incorporating different resiliency readiness profiles matched to tailored resilience training. Will conduct studies to validate cognitive bias modification tools to improve behavioral health and performance. Will conduct clinical field trial of a repurposed FDA approved drug for treating sleep problems in a deployed setting. Will deliver biologically based biomarkers for onset of stress disorders and for resilience to stress disorders. Will fund clinical trials evaluating effectiveness of provider tool-kit for behavioral health return to duty (RTD) decision making and clinical trials for brief far-forward interventions for behavioral health problems and accompanying provider training in their use.</p> <p><b>FY 2019 to FY 2020 Increase/Decrease Statement:</b> Ongoing work realigned from other project due to S&amp;T Financial Restructuring. In FY 2020, reduced funding for Psychological Health and Resilience is due to reduced funding for Psychiatry &amp; Clinical Psychology Disorders due to realignment of funds away from USACEHR Systems Biology for PTSD to new high priority programs within MRMC.</p>					
<p><b>Title:</b> Environmental Health &amp; Protection</p> <p><b>Description:</b> This effort supports and matures non-invasive technologies, decision-aid tools, and models to enhance Soldier protection and sustainment across the operational spectrum. The aim is to provide the scientific basis for developing focused heating and cooling solutions to maintain fine motor dexterity, core temperature, and optimized physical and cognitive performance during cold-weather and hot-humid operations. This effort tests a computational algorithm for identifying latent hepatic, renal, and cardiac injury after toxic metal and/or toxic industrial chemical exposure during training and operations. This effort tests models to predict likelihood of neurologic and/or physical injury as a result of hazardous exposure(s) in the operational environment.</p>			-	-	1.914

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2020 Army		<b>Date:</b> March 2019	
<b>Appropriation/Budget Activity</b> 2040 / 3	<b>R-1 Program Element (Number/Name)</b> PE 0603002A / <i>Medical Advanced Technology</i>	<b>Project (Number/Name)</b> MG4 / <i>Tech Base/Enabling Res in Mil Occup Med Adv Tech</i>	
<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>		<b>FY 2018</b>	<b>FY 2019</b>
<p><b><i>FY 2020 Plans:</i></b>  Will provide validated tools that sustain lethality and optimize performance to prevent injuries related to multi-environmental stressors. Will provide a capability to improve performance and thermal comfort in hot environments using cooling technology with skin temperature feedback control. Will provide a capability to increase finger and toe temperatures to improve manual dexterity and performance in cold weather operations. Will provide a capability a measure of cognitive fatigue due to sustained, effortful cognitive activity (workload) from exposure to stress and environmental extremes. Will provide accurate signal detection of toxic environmental hazards and physiological algorithms to detect degraded performance post-chemical exposure. Will provide a capability for mission planning and the documenting of toxic chemical or hazardous material exposures. Will provide risk management criteria for Commanders/leaders to make decisions in real-time regarding the severity of the exposure and the likelihood of clinical manifestation of a toxic exposure.</p> <p><b><i>FY 2019 to FY 2020 Increase/Decrease Statement:</i></b>  Ongoing work realigned from other project due to S&amp;T Financial Restructuring. In FY 2020 funding decreased due to movement of some of the funds from Operational Exposure Dosimetry for Neurological and Physical Health.</p>			
<b>Accomplishments/Planned Programs Subtotals</b>		-	8.144
<b>C. Other Program Funding Summary (\$ in Millions)</b>			
N/A			
<b>Remarks</b>			
<b>D. Acquisition Strategy</b>			
N/A			
<b>E. Performance Metrics</b>			
N/A			

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2020 Army										<b>Date:</b> March 2019		
<b>Appropriation/Budget Activity</b> 2040 / 3					<b>R-1 Program Element (Number/Name)</b> PE 0603002A / <i>Medical Advanced Technology</i>				<b>Project (Number/Name)</b> MM2 / <i>MEDICAL ADVANCE TECHNOLOGY INITIATIVES (CA)</i>			
<b>COST (\$ in Millions)</b>	<b>Prior Years</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020 Base</b>	<b>FY 2020 OCO</b>	<b>FY 2020 Total</b>	<b>FY 2021</b>	<b>FY 2022</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>Cost To Complete</b>	<b>Total Cost</b>
MM2: <i>MEDICAL ADVANCE TECHNOLOGY INITIATIVES (CA)</i>	-	8.000	8.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	16.000

**Note**  
Congressional increase for Peer-reviewed military burn research.

**A. Mission Description and Budget Item Justification**  
Congressional Interest Item funding for Medical Advanced Technology Initiatives.

<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>	<b>FY 2018</b>	<b>FY 2019</b>
<b>Congressional Add:</b> Peer-reviewed Military Burn Research Program	8.000	8.000
<b>FY 2018 Accomplishments:</b> Peer-reviewed Military Burn Research Program		
<b>FY 2019 Plans:</b> Peer-reviewed Military Burn Research Program		
<b>Congressional Adds Subtotals</b>	8.000	8.000

**C. Other Program Funding Summary (\$ in Millions)**  
N/A

**Remarks**

**D. Acquisition Strategy**  
N/A

**E. Performance Metrics**  
N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Army										Date: March 2019		
Appropriation/Budget Activity 2040 / 3					R-1 Program Element (Number/Name) PE 0603002A / Medical Advanced Technology				Project (Number/Name) MM3 / Warfighter Medical Protection & Performance			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
MM3: Warfighter Medical Protection & Performance	-	19.563	16.894	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	36.457

## Note

In Fiscal Year (FY) 2020 this Project was realigned to:

Program Element (PE) 0603002A Medical Advanced Technology, Projects:

- \* MG4 Tech Base/Enabling Research In Military Occupational Medicine Advanced Technology
- \* MN6 Blast & Head Impact Exposure Monitor Advanced Technology
- \* MN7 Musculoskeletal Injury Screening Tool Advanced Technology
- \* MN9 Far Forward Behavioral Health Care Advanced Technology
- \* MO3 Military Occupational Fitness Standards Advanced Technology
- \* MO8 Expeditionary Performance Nutrition Advanced Technology

## A. Mission Description and Budget Item Justification

This Project supports the medical and survivability technology areas of the future force with laboratory validation studies and field demonstrations of biomedical products designed to protect, sustain, and enhance Soldier performance in the face of myriad environmental and physiological (human physical and biochemical functions) stressors and materiel hazards encountered in training and operational environments. This effort focuses on demonstrating and transitioning technologies as well as validated tools associated with biomechanical-based health risks, injury assessment and prediction, Soldier survivability, and performance during continuous operations.

The four main thrust areas are:

- (1) Physiological Health,
- (2) Environmental Protection,
- (3) Injury Prevention and Reduction
- (4) Psychological (mental) Health and Resilience.

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

The cited work is consistent with the Under Secretary of Defense (Research and Engineering) science and technology focus areas and the Army Modernization Strategy. All FY 2020 adjustments align program resources to Army Modernization Priorities in support of the National Defense Strategy.

Work in this Project is performed by: the U.S. Army Medical Research Materiel Command (USAMRMC), Fort Detrick, MD.

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Army		Date: March 2019		
Appropriation/Budget Activity 2040 / 3	R-1 Program Element (Number/Name) PE 0603002A / Medical Advanced Technology	Project (Number/Name) MM3 / Warfighter Medical Protection & Performance		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2018	FY 2019	FY 2020
<b>Title:</b> Physiological (human physical and biochemical functions) Health and Environmental Protection (Sleep Research/ Environmental Monitoring)  <b>Description:</b> This effort supports and matures laboratory prototypes, nutritional interventions, and decision aids for the validation of physiological status and prediction of Soldier performance in extreme environments. This effort supports Capability Demonstration 1.b, Force Protection--Warfighter and Small Unit in FY 2014-2016 and also supports capability demonstrations in the area of decreasing Warfighter physical burden in FY 2014-2016. Starting in FY 2019 this effort moves to Physiological Health.		7.083	-	-
<b>Title:</b> Physiological Health  <b>Description:</b> This effort supports and matures laboratory prototypes, nutritional formulations and interventions, and decision aids for the validation of physiological status and prediction of Soldier performance in extreme environments.  <b>FY 2019 Plans:</b> Evaluate interventions to mitigate sleep loss and fatigue and improve individual and team performance in operational settings, including multi-domain battle scenarios. Demonstrate effectiveness of transcranial electrical stimulation of the prefrontal cortex for enhancing learning through the consolidation of emotional memories. Evaluate the utility and effectiveness of transcranial direct current electrical stimulation technologies as neurocognitive interventions for the enhancement of the recuperative sleep and the development of operationally relevant sleep strategies. Validate dietary interventions for promoting satisfaction and healthy eating in dining facilities to ensure optimal health and performance.  <b>FY 2019 to FY 2020 Increase/Decrease Statement:</b> FY 2020 funds were realigned to new projects MG4, and MO8		-	2.602	-
<b>Title:</b> Environmental Health and Protection - Physiological (human physical and biochemical functions) Awareness Tools and Warrior Sustainment in Extreme Environments.  <b>Description:</b> This effort supports and maturates non-invasive technologies, decision-aid tools, and models to enhance Warfighter protection and sustainment across the operational spectrum. This effort provides the scientific basis for developing focused heating and cooling solutions to maintain fine motor dexterity, core temperature, and optimize physical and cognitive performance during cold-weather and hot-humid operations. Starting in FY 2019 this effort is combined into Environmental and Protection.		2.822	-	-
<b>Title:</b> Environmental Health & Protection  <b>Description:</b> This effort supports and maturates non-invasive technologies, decision-aid tools, and models to enhance Soldier protection and sustainment across the operational spectrum. The aim is to provide the scientific basis for developing focused heating and cooling solutions to maintain fine motor dexterity, core temperature, and optimized physical and cognitive performance during cold-weather and hot-humid operations. This effort tests a computational algorithm for identifying latent		-	5.588	-



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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2020 Army			<b>Date:</b> March 2019		
<b>Appropriation/Budget Activity</b> 2040 / 3		<b>R-1 Program Element (Number/Name)</b> PE 0603002A / <i>Medical Advanced Technology</i>		<b>Project (Number/Name)</b> MM3 / <i>Warfighter Medical Protection &amp; Performance</i>	
<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>			<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>
<p>hepatic, renal, and cardiac injury after toxic metal and/or toxic industrial chemical exposure during training and operations. This effort tests models to predict likelihood of neurologic and/or physical injury as a result of hazardous exposure(s) in the operational environment.</p> <p><b>FY 2019 Plans:</b> Provide evidence-based practice recommendations for protecting health and performance against combined environmental threats. Develop enhanced next generation of predictive algorithms for incorporation into wearable sensor systems. Transition the Cold Weather Ensemble Decision Aid (CWEDA) to PEO Soldier and US Army Alaska, for assessing and comparing different clothing ensembles for predicting cold weather endurance. Validate prototype focused heating capability to improve manual dexterity for individuals in cold weather operations. Transition prototypes such as the Heat Strain Decision Application (HSDApp) to JPEO-Chemical Biological Defense, PEO Soldier, and Army Public Health Center. Evaluate modeling paradigms which identify population subgroups at increased risk of military operational exposure-related health responses. Develop and enhance a next generation of health, readiness and performance predictive algorithms for incorporation into wearable sensors systems. Validate assessment technologies/tools for physical and/or neurological health outcomes in operational environments.</p> <p><b>FY 2019 to FY 2020 Increase/Decrease Statement:</b> FY 2020 funds were realigned to new project MG4</p>					
<p><b>Title:</b> Injury Prevention and Reduction</p> <p><b>Description:</b> This effort supports and validates injury prediction tools and return-to-duty assessments for brain, spine, and chest injury from blast, blunt, and ballistic impact. This effort also addresses need for validated aeromedical standards and strategies to enable aircrew to effectively fight, navigate, and land under a range of degraded visual environments and provide aeromedical return to duty guidelines after neurosensory injury (deficits in the nervous system control of vision, hearing, taste, smell, and touch).</p> <p><b>FY 2019 Plans:</b> Use human head impact/blast and clinical diagnosis of mild traumatic brain injuries (mTBIs) within the training environment (e.g., airborne operations, combatives) to improve and validate mTBI prediction algorithms that can be used for the development of improved head protection systems. Validate musculoskeletal injury risk models with data collected from training and theatre. Determine cervical spine injury risk (Head Supported Mass Criteria) leveraging methods used by personal protective equipment developers to measure impact of clothing and equipment such as the Army's Load Effects Assessment Program (LEAP). Evaluate and extend current auditory injury risk models to include auditory nerve damage and begin to evaluate with advanced animal models. Improve current guidance using results from computational models and animal studies for protective eyewear against</p>			5.168	5.058	-

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Army		Date: March 2019		
Appropriation/Budget Activity 2040 / 3	R-1 Program Element (Number/Name) PE 0603002A / Medical Advanced Technology	Project (Number/Name) MM3 / Warfighter Medical Protection & Performance		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2018	FY 2019	FY 2020
blast threats that will inform the Authorized Protective Eyewear List (APEL). Validate medical requirements that will inform Army Aviation fitness for duty requirements				
FY 2019 to FY 2020 Increase/Decrease Statement: FY 2020 funds were realigned to new projects MG4, MN7, MO3, and MN6				
Title: Psychological Health and Resilience  Description: This effort supports and validates neurocognitive (relating to or involving the central nervous system and cognitive abilities) assessment and brain injury detection methods, and validates tools and preclinical methods to treat post-traumatic stress disorder in a military population. This effort also supports validation of interventions in Warfighters for post-traumatic stress disorder (PTSD), validation of biomarkers of individual PTSD symptoms, validation of methods to follow effectiveness of PTSD treatments, validation of neuroprotective (protection of nerves and nervous system) interventions and validation of strategies to prevent neurocognitive deficits (reduced ability to learn and comprehend) and symptomatology associated with brain injury.  FY 2019 Plans: Refine the Unit Behavioral Health Needs Assessment tool with metrics from combat operations, non-combat operations, and garrison. Evaluate an evidence-based, team-level intervention that positively influences Soldier outcomes related to behavioral health, resilience, and unit readiness through the regulation of small-team dynamics (e.g., group effect). Evaluate effectiveness of experimental compounds for PTSD symptom alleviation. Continue characterizations of PTSD subtyping and collection of treatment associated blood specimens for development of precision medicine approaches to PTSD treatment. Transition assessment tools to providers to augment return-to-duty decisions. Transition to behavioral health providers a web-based model for dissemination of research findings addressing evidence-based PTSD treatments.  FY 2019 to FY 2020 Increase/Decrease Statement: FY 2020 funds were realigned to new projects MG4 and MN9		3.536	3.201	-
Title: Health Research  Description: This effort develops and validates novel tools and strategies to advance individualized operational exposure dosimetry (measures of exposure) and establish dose-response links between operational exposures and neurological and physical health. Dosimetry tools may include new technologies, human biomarkers objective physiologic markers, physiological modeling, and validated algorithms to evaluate the health effects of military service, including deployments, and methods to detect a Warfighters exposure to environmental contamination and/or toxic substances, e.g. toxic industrial chemicals. Starting in FY 2019 this effort is combined into Environmental Health & Protection.		0.954	-	-
Title: FY 2019 SBIR / STTR Transfer		-	0.445	-

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2020 Army		<b>Date:</b> March 2019	
<b>Appropriation/Budget Activity</b> 2040 / 3	<b>R-1 Program Element (Number/Name)</b> PE 0603002A / <i>Medical Advanced Technology</i>	<b>Project (Number/Name)</b> MM3 / <i>Warfighter Medical Protection &amp; Performance</i>	
<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>		<b>FY 2018</b>	<b>FY 2019</b>
<b><i>FY 2019 Plans:</i></b> FY 2019 SBIR / STTR Transfer			
<b><i>FY 2019 to FY 2020 Increase/Decrease Statement:</i></b> FY 2019 SBIR / STTR Transfer			
<b>Accomplishments/Planned Programs Subtotals</b>		19.563	16.894
<b>C. Other Program Funding Summary (\$ in Millions)</b> N/A			
<b>Remarks</b>			
<b>D. Acquisition Strategy</b> N/A			
<b>E. Performance Metrics</b> N/A			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Army										Date: March 2019		
Appropriation/Budget Activity 2040 / 3					R-1 Program Element (Number/Name) PE 0603002A / Medical Advanced Technology				Project (Number/Name) MM5 / Tech Base/Enabling Res Combat Cas Care Adv Tech			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
MM5: Tech Base/Enabling Res Combat Cas Care Adv Tech	-	0.000	0.000	2.408	-	2.408	2.795	3.249	3.651	6.914	0.000	19.017
Note In Fiscal Year (FY) 2020, this Project was realigned from: Program Element (PE) 0603002A Medical Advanced Technology * Project 840 Combat Injury Mgmt.												
A. Mission Description and Budget Item Justification Preclinical and early clinical development, demonstration, and transition of new combat casualty care technologies that save lives and minimize permanent injury following combat-related traumatic injuries. Focus is identifying more effective critical care technologies and clinical practice guidelines to treat severe bleeding, traumatic brain injury, burns and other combat related traumatic injuries.  All research is conducted in compliance with Food and Drug Administration (FDA) requirements for licensure of medical products for human use.  Promising efforts identified through applied research conducted under PE 0602787A, Project 874, are further matured under this Project. Promising results identified under this Project are further matured under PE 0603807A, Project 836.  The cited work is consistent with the Under Secretary of Defense (Research and Engineering) science and technology focus areas and the Army Modernization Strategy. All FY20 adjustments align program resources to Army Modernization Priorities in support of the National Defense Strategy.  Work in this Project is performed by: the U.S. Army Medical Research Materiel Command (USAMRMC), Fort Detrick, MD.												
B. Accomplishments/Planned Programs (\$ in Millions)									FY 2018	FY 2019	FY 2020	
Title: Combat Trauma Therapies									-	-	1.060	
Description: This effort focuses on work required to validate safety and effectiveness of drugs, biologics, and medical procedures intended to minimize immediate and long-term effects from battlefield injuries.												
FY 2020 Plans: Will continue studies in animals to evaluate effectiveness of products to combat wound infection, inflammation and scarring of delayed wound healing.												
FY 2019 to FY 2020 Increase/Decrease Statement:												

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2020 Army			<b>Date:</b> March 2019		
<b>Appropriation/Budget Activity</b> 2040 / 3		<b>R-1 Program Element (Number/Name)</b> PE 0603002A / <i>Medical Advanced Technology</i>		<b>Project (Number/Name)</b> MM5 / <i>Tech Base/Enabling Res Combat Cas Care Adv Tech</i>	
<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>			<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>
Funds for ongoing work were realigned from Project 840 / Combat Trauma Therapies					
<b>Title:</b> Pre-Hospital Tactical Combat Casualty Care  <b>Description:</b> This effort supports demonstration and validation of materiel and knowledge products to advance the level of care that can be provided given the tactical, environmental, and patient factors inherent in the prehospital combat setting. Successful translation of research to the field will augment combat medic capabilities, thereby reducing death and serious injury in the battlefield space where the majority of preventable casualty deaths occur.  <b>FY 2020 Plans:</b> Will begin clinical testing of an automated system for assessing injury severity.  <b>FY 2019 to FY 2020 Increase/Decrease Statement:</b> Funds for ongoing work were realigned from Project 840 / Combat Critical Care Engineering			-	-	0.484
<b>Title:</b> Traumatic Brain Injury  <b>Description:</b> This effort supports work required to validate safety and effectiveness of drugs, biologics, and medical procedures intended to minimize immediate and long-term effects from TBI.  <b>FY 2020 Plans:</b> Will evaluate alternative therapies that promote brain-remodeling and restoration of function following severe TBI.  <b>FY 2019 to FY 2020 Increase/Decrease Statement:</b> Funds for ongoing work were realigned from Project 840 / Traumatic Brain Injury (TBI)			-	-	0.864
<b>Accomplishments/Planned Programs Subtotals</b>			-	-	2.408
<b>C. Other Program Funding Summary (\$ in Millions)</b> N/A					
<b>Remarks</b>					
<b>D. Acquisition Strategy</b> N/A					
<b>E. Performance Metrics</b> N/A					

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Army										Date: March 2019		
Appropriation/Budget Activity 2040 / 3					R-1 Program Element (Number/Name) PE 0603002A / Medical Advanced Technology				Project (Number/Name) MM7 / Enabling Med Cap to Support Dispersed OPS Adv Tech			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
MM7: Enabling Med Cap to Support Dispersed OPS Adv Tech	-	0.000	0.000	1.819	-	1.819	3.851	4.826	4.778	5.000	0.000	20.274
Note This Project is a new start in Fiscal Year (FY) 2020.												
A. Mission Description and Budget Item Justification This Project is a new start for FY 2020 designed to mature Applied Research first developed in PE 0602787A (Medical Technology) / Project XV5 (Medical Capabilities to Support Dispersed Ops).  The aim of this Project is to develop a data-driven, intelligent and autonomous combat evacuation medical capability by maturing relevant artificial intelligence (AI) and machine learning algorithms and processes. These efforts will support initial and sustained integrated theater health care and trauma care delivery in future dispersed operations characterized by delayed evacuation, prolonged care, and reduced/denied communications. AI and machine learning technologies developed in this Project aim to reduce military combat casualties by enabling autonomous evacuation utilizing future Army Unmanned Aerial System (UAS) and ground platforms. Pursuant to these aims, this Project will research and design a tele-monitored and remote-controlled medical module to support medical resupply and casualty evacuation. The medical module will be developed to be self-contained, providing a "roll-on, roll-off" medical capability to future multi-purpose UAS and ground platforms.  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 (U.S.) Army Medical Research Materiel Command (USAMRMC), Fort Detrick, MD.												
B. Accomplishments/Planned Programs (\$ in Millions)									FY 2018	FY 2019	FY 2020	
Title: Combat Evacuation Mission Module									-	-	1.819	
Description: Research, design and develop a tele-monitored and remote-controlled Combat Evacuation Mission Module to support medical resupply and casualty evacuation using future multi-purpose vertical takeoff and landing (VTOL) Unmanned Aerial Systems (UAS). Provides a self-contained medical module capability adaptable to various future multi-purpose VTOL UAS.												
FY 2020 Plans: Will complete vehicle flight instrumentation of the first generation Combat Evacuation Mission Module prototype for calibration and check out in preparation for flight testing. Will complete flight test plans, procure test components, and prepare the Medical Module for transport to the flight test facility.												

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2020 Army		<b>Date:</b> March 2019	
<b>Appropriation/Budget Activity</b> 2040 / 3	<b>R-1 Program Element (Number/Name)</b> PE 0603002A / <i>Medical Advanced Technology</i>	<b>Project (Number/Name)</b> MM7 / <i>Enabling Med Cap to Support Dispersed OPS Adv Tech</i>	
<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>		<b>FY 2018</b>	<b>FY 2019</b>
<p>Will construct a full-sized mock-up of the second generation Combat Evacuation Mission Module, based on current Objective vehicle UAS design, using rapid-prototyping capabilities to begin the determination of equipment configurations, placements, implementations, and interface requirements. Will medically-equip the mock-up second generation Mission Module using conceptual representations/ prototypes of emerging systems for remotely operated, or semi-autonomous/closed-loop patient monitoring, diagnostic, and intervention that would either support an attending medic during en route care or provide a remote en route care capability if there is no medic available to attend during transport.</p> <p><b><i>FY 2019 to FY 2020 Increase/Decrease Statement:</i></b> New start for FY 2020 to mature 0602787A / XV5 efforts developed in FY 2019.</p>			
<b>Accomplishments/Planned Programs Subtotals</b>		-	1.819
<b>C. Other Program Funding Summary (\$ in Millions)</b> N/A			
<b>Remarks</b>			
<b>D. Acquisition Strategy</b> N/A			
<b>E. Performance Metrics</b> N/A			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Army										Date: March 2019		
Appropriation/Budget Activity 2040 / 3					R-1 Program Element (Number/Name) PE 0603002A / Medical Advanced Technology				Project (Number/Name) MM9 / Tech Base/Enabling Rsrch for Infect Dis Adv Tech			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
MM9: Tech Base/Enabling Rsrch for Infect Dis Adv Tech	-	0.000	0.000	2.976	-	2.976	2.979	4.376	7.607	7.488	0.000	25.426
Note In Fiscal Year (FY) 2020 this Project was realigned from: Program Element (PE) 0603002A Medical Advanced Technology * Project 810 Ind Base Id Vacc & Drug												
A. Mission Description and Budget Item Justification Technology development, demonstration, and transition of FDA-regulated medical countermeasures such as drugs and vaccines to naturally-occurring infectious diseases of military importance, as identified by worldwide medical surveillance and capability needs assessments.  Research is conducted in compliance with FDA regulations for medical products for human use.  Work is managed by the United States Army Medical Research and Materiel Command (USAMRMC) in coordination with the Naval Medical Research Center (NMRC). The Army is responsible for programming and funding all Department of Defense (DoD) naturally occurring infectious disease research requirements, thereby precluding duplication of effort within the Military Departments.  Promising medical countermeasures identified in this Project are further matured under Program Element 0603807A, Project 808.  The cited work is consistent with the Under Secretary of Defense (Research and Engineering) science and technology focus areas and the Army Modernization Strategy. All FY20 adjustments align program resources to Army Modernization Priorities in support of the National Defense Strategy.  Work in this Project is performed by: the U.S. Army Medical Research Materiel Command (USAMRMC), Fort Detrick, MD.  Efforts in this Project support the Soldier portfolio and the principal area of Military Relevant Infectious Diseases.												
B. Accomplishments/Planned Programs (\$ in Millions)									FY 2018	FY 2019	FY 2020	
Title: Advanced Technology Research on drugs and vaccines against parasitic diseases									-	-	1.408	
Description: Test lead drug candidates in healthy volunteers to determine drug pharmacology, safety, and effectiveness against malaria. Transition the lead anti-malarial drug with improved safety, effectiveness and less frequent dosing to advanced												



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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2020 Army		<b>Date:</b> March 2019	
<b>Appropriation/Budget Activity</b> 2040 / 3	<b>R-1 Program Element (Number/Name)</b> PE 0603002A / <i>Medical Advanced Technology</i>	<b>Project (Number/Name)</b> MM9 / <i>Tech Base/Enabling Rsrch for Infect Dis Adv Tech</i>	
<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>		<b>FY 2018</b>	<b>FY 2019</b>
development. Perform small studies in healthy volunteers to test vaccine safety, effectiveness and immunogenicity against malaria with down-selection and transition of the vaccines to advanced development.			
<b>FY 2020 Plans:</b> Will initiate safety and analytic studies to assess natural break-down of candidate drugs within the human body to improve drug safety and effectiveness for treatment and prevention of malaria for selected triazine lead compound. Will complete clinical trials to assess performance of lead Plasmodium falciparum malaria vaccine candidates. These activities enable down- selection of a lead vaccine for transition to advanced development. Will validate laboratory-based immune measures of protection and correlate with protective effectiveness among candidate vaccines undergoing clinical trials.			
<b>FY 2019 to FY 2020 Increase/Decrease Statement:</b> Ongoing work transferred from other project due to S&T Financial Restructuring.			
<b>Title:</b> Viral Disease Threats  <b>Description:</b> Perform small studies in healthy volunteers to test vaccine safety, effectiveness, and immunogenicity against Dengue and Hantaviruses infections so as to down-select and transition lead vaccine candidates to advanced development.		-	-
<b>FY 2020 Plans:</b> Will continue to evaluate safety and initial effectiveness of commercial partner dengue vaccine candidates undergoing testing in Southeast Asia and Latin America. Will continue to complete vaccine immunogenicity (ability to provoke an immune response) testing followed by dengue human infection model challenge and effectiveness testing of human subjects immunized with combination inactivated and weakened forms of virus vaccines. Will continue to engage commercial partner to pursue development of purified inactivated dengue virus in combination with live attenuated product. Will continue to pursue an expanded Hemorrhagic Fever with Renal Syndrome (HFRS) DNA vaccine clinical trial in a country/region that has endemic HFRS cases. Will continue to test for safety and effectiveness of the HFRS DNA vaccine.			
<b>FY 2019 to FY 2020 Increase/Decrease Statement:</b> Ongoing work transferred from other project due to S&T Financial Restructuring.			
<b>Accomplishments/Planned Programs Subtotals</b>		-	-
<b>C. Other Program Funding Summary (\$ in Millions)</b>			
N/A			
<b>Remarks</b>			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Army		Date: March 2019
Appropriation/Budget Activity 2040 / 3	R-1 Program Element (Number/Name) PE 0603002A / Medical Advanced Technology	Project (Number/Name) MM9 / Tech Base/Enabling Rsrch for Infect Dis Adv Tech
D. Acquisition Strategy N/A		
E. Performance Metrics N/A		

# UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2020 Army										Date: March 2019		
Appropriation/Budget Activity 2040 / 3					R-1 Program Element (Number/Name) PE 0603002A / Medical Advanced Technology				Project (Number/Name) MN3 / Immediate Cardiopulmonary Stabilization Adv Tech			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
MN3: Immediate Cardiopulmonary Stabilization Adv Tech	-	0.000	0.000	1.903	-	1.903	1.894	1.808	1.895	1.940	0.000	9.440
<b>Note</b> In Fiscal Year (FY) 2020 this Project was realigned from: Program Element (PE) 0603002A Medical Advanced Technology * Project 840 Combat Injury Mgmt												
<b>A. Mission Description and Budget Item Justification</b> This Project covers development, pre-clinical and early-clinical demonstration, and transition of technologies for hemorrhage control and airway management. These technologies facilitate autonomous intubation and airway management in combat casualties with obstructed airways. This Project also covers advanced technologies for use in forward areas to control non-compressible torso hemorrhage, and demonstration of pain-relieving drugs that are safe for use during bleeding.  Promising efforts identified through Applied Research conducted under PE 0602787A, Project MM4 are further matured under this Project. Promising results identified under this Project are further matured under PE 0603807A, Project 836.  The cited work is consistent with the Under Secretary of Defense (Research and Engineering) science and technology focus areas and the Army Modernization Strategy. All FY 2020 adjustments align program resources to Army Modernization Priorities in support of the National Defense Strategy.  Work in this Project is performed by: the U.S. Army Medical Research Materiel Command (USAMRMC), Fort Detrick, MD.												
<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>									FY 2018	FY 2019	FY 2020	
<b>Title:</b> Device Product Candidates for Immediate Cardiopulmonary Stabilization									-	-	1.903	
<b>Description:</b> Development, preclinical and early-clinical demonstration, and transition of technologies that facilitate autonomous intubation and airway management in combat casualties with obstructed airways, as well as advanced hemostatic bandage candidates that augment the patient's blood clotting system and new tourniquet technologies suitable for prolonged use.												
<b>FY 2020 Plans:</b>												

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2020 Army		<b>Date:</b> March 2019	
<b>Appropriation/Budget Activity</b> 2040 / 3	<b>R-1 Program Element (Number/Name)</b> PE 0603002A / <i>Medical Advanced Technology</i>	<b>Project (Number/Name)</b> MN3 / <i>Immediate Cardiopulmonary Stabilization Adv Tech</i>	
<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>		<b>FY 2018</b>	<b>FY 2019</b>
Will conduct preclinical and early clinical evaluation of devices indicated for use to facilitate autonomous intubation and airway management in combat casualties with obstructed airways, advanced hemostatic dressings that are effective independent of the patient's blood clotting system, as well as new tourniquet technologies having prolonged effectiveness.			
<b>FY 2019 to FY 2020 Increase/Decrease Statement:</b> Funds for ongoing work were realigned from Project 840 / Combat Trauma Therapies			
<b>Accomplishments/Planned Programs Subtotals</b>		-	1.903
<b>C. Other Program Funding Summary (\$ in Millions)</b> N/A			
<b>Remarks</b>			
<b>D. Acquisition Strategy</b> N/A			
<b>E. Performance Metrics</b> N/A			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Army										Date: March 2019			
Appropriation/Budget Activity 2040 / 3					R-1 Program Element (Number/Name) PE 0603002A / Medical Advanced Technology				Project (Number/Name) MN4 / Advanced Life Support Advanced Technology				
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost	
MN4: Advanced Life Support Advanced Technology	-	0.000	0.000	3.801	-	3.801	3.397	4.531	5.109	5.185	0.000	22.023	
Note In Fiscal Year (FY) 2020 this Project was realigned from: Program Element (PE) 0603002A Medical Advanced Technology * Project 840 Combat Injury Mgmt													
A. Mission Description and Budget Item Justification This Project covers development, demonstration, and transition of technologies that enable advanced life support under prolonged field care scenarios, including: life-support devices that provide lung and kidney functions in casualties with severe injuries; and devices and clinical guidelines for the prevention of irreversible organ damage resulting from prolonged lack of blood circulation.  All research is conducted in compliance with Food and Drug Administration (FDA) requirements for licensure of medical products for human use.  Promising efforts identified through Applied Research conducted under PE 0602787A, Project MM4 are further matured under this Project. Promising results identified under this Project are further matured under PE 0603807A, Project 836.  The cited work is consistent with the Under Secretary of Defense (Research and Engineering) science and technology focus areas and the Army Modernization Strategy. All FY 2020 adjustments align program resources to Army Modernization Priorities in support of the National Defense Strategy.  Work in this Project is performed by: the U.S. Army Medical Research Materiel Command (USAMRMC), Fort Detrick, MD.													
B. Accomplishments/Planned Programs (\$ in Millions)									FY 2018	FY 2019	FY 2020		
Title: Technology Product Demonstration for Advanced Life Support									-	-	3.801		
Description: Development, demonstration, and transition of technologies that enable advanced life support under prolonged field care scenarios: life-support devices that provide lung and kidney functions in casualties with severe injuries; devices and clinical guidelines for the prevention of irreversible organ damage resulting from prolonged lack of blood circulation.													
FY 2020 Plans: Will demonstrate devices indicated for use to control oxygen and carbon dioxide exchange in casualties with acute lung injury, and/or to deliver blood purification in critically injured/ill casualties with acute kidney injury. Will demonstrate improved means to control bleeding within the chest and abdomen through use of a specialized catheter that maintains normal blood pressure													

# UNCLASSIFIED

<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2020 Army		<b>Date:</b> March 2019	
<b>Appropriation/Budget Activity</b> 2040 / 3	<b>R-1 Program Element (Number/Name)</b> PE 0603002A / <i>Medical Advanced Technology</i>	<b>Project (Number/Name)</b> MN4 / <i>Advanced Life Support Advanced Technology</i>	
<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>		<b>FY 2018</b>	<b>FY 2019</b>
within the brain, heart and lungs and minimizes lack of blood flow to other organs and lower body until definitive surgical care is available.			
<b>FY 2019 to FY 2020 Increase/Decrease Statement:</b> Funds for ongoing work were realigned from PE 0603002A Project 840 (Combat Injury Mgt) - Task #4/Prolonged Field Care			
<b>Accomplishments/Planned Programs Subtotals</b>		-	3.801
<b>C. Other Program Funding Summary (\$ in Millions)</b> N/A			
<b>Remarks</b>			
<b>D. Acquisition Strategy</b> N/A			
<b>E. Performance Metrics</b> N/A			

# UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2020 Army										Date: March 2019		
Appropriation/Budget Activity 2040 / 3					R-1 Program Element (Number/Name) PE 0603002A / Medical Advanced Technology				Project (Number/Name) MN5 / Next Generation Blood Products Advanced Technology			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
MN5: Next Generation Blood Products Advanced Technology	-	0.000	0.000	5.964	-	5.964	6.634	6.752	6.972	7.056	0.000	33.378

**Note**

In Fiscal Year (FY) 2020 this Project was realigned from:  
Program Element (PE) 0603002A Medical Advanced Technology  
\* Project 840 Combat Injury Mgmt

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

This Project covers technology development, pre-clinical and early-clinical demonstration, and transition of new blood products with increased shelf life and functionality. Cold-stored platelets, fibrinogen replacement technologies, and pharmaceuticals that protect and metabolically stabilize blood-deprived tissues will improve prompt hemorrhage control, mitigate effects of shock, and minimize sustainment requirements.

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

Promising efforts identified through Applied Research conducted under PE 0602787A, Project MM4 are further matured under this Project. Promising results identified under this Project are further matured under PE 0603807A, Project 836.

The cited work is consistent with the Under Secretary of Defense (Research and Engineering) science and technology focus areas and the Army Modernization Strategy. All FY20 adjustments align program resources to Army Modernization Priorities in support of the National Defense Strategy.

Work in this Project is performed by: the U.S. Army Medical Research Materiel Command (USAMRMC), Fort Detrick, MD.

<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>
<b>Title:</b> Next Generation Biopharmaceutical Product Candidates for Hemostasis	-	-	5.964
<b>Description:</b> Technology development, pre-clinical and early-clinical demonstration, and transition of new blood products with increased shelf life and functionality. Cold-stored platelets and fibrinogen replacement technologies will improve prompt hemorrhage control and minimize sustainment requirements.			
<b>FY 2020 Plans:</b>			

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2020 Army		<b>Date:</b> March 2019	
<b>Appropriation/Budget Activity</b> 2040 / 3	<b>R-1 Program Element (Number/Name)</b> PE 0603002A / <i>Medical Advanced Technology</i>	<b>Project (Number/Name)</b> MN5 / <i>Next Generation Blood Products Advanced Technology</i>	
<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>		<b>FY 2018</b>	<b>FY 2019</b>
Will demonstrate preclinical and early clinical technologies to optimize shelf life and functionality of cold stored platelets, and pharmacologic replacement of fibrinogen to assist early hemorrhage control.			
<b>FY 2019 to FY 2020 Increase/Decrease Statement:</b> Funds for ongoing work were realigned from Project 840 / Damage Control Resuscitation			
<b>Accomplishments/Planned Programs Subtotals</b>		-	5.964
<b>C. Other Program Funding Summary (\$ in Millions)</b> N/A			
<b>Remarks</b>			
<b>D. Acquisition Strategy</b> N/A			
<b>E. Performance Metrics</b> N/A			



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Exhibit R-2A, RDT&E Project Justification: PB 2020 Army										Date: March 2019																						
Appropriation/Budget Activity 2040 / 3					R-1 Program Element (Number/Name) PE 0603002A / Medical Advanced Technology				Project (Number/Name) MN6 / Blast & Head Impact Exposure Monitor Advanced Tech																							
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost																				
MN6: Blast & Head Impact Exposure Monitor Advanced Tech	-	0.000	0.000	1.412	-	1.412	1.412	1.412	0.000	0.000	0.000	4.236																				
<div>Note</div> <div>In Fiscal Year (FY) 2020 this Project was realigned from: Program Element (PE) 0603002A Medical Advanced Technology * Project MM3 Warfighter Medical Protection &amp; Performance</div> <div>A. Mission Description and Budget Item Justification</div> <div>This effort will develop a prototype predictive tool that can provide the unit leader an indication of whether a potential mild traumatic brain injury event has occurred. This capability will provide the unit leader an additional objective tool to determine whether a Soldier can be safely be exposed to more impacts without increased risk of injury.</div> <div>The cited work is fully coordinated with Natick Soldier Research Development (NSRDEC), Natick, MA and with other Services in order to avoid duplication of effort.</div> <div>The cited work is consistent with the Under Secretary of Defense (Research and Engineering) science and technology focus areas and the Army Modernization Strategy. All FY20 adjustments align program resources to Army Modernization Priorities in support of the National Defense Strategy.</div> <div>Work in this Project is performed by: the U.S. Army Medical Research Materiel Command (USAMRMC), Fort Detrick, MD.</div> <div>B. Accomplishments/Planned Programs (\$ in Millions)</div> <table><tr><td></td><td>FY 2018</td><td>FY 2019</td><td>FY 2020</td></tr><tr><td>Title: Blast &amp; Head Impact Exposure Monitor</td><td>-</td><td>-</td><td>1.412</td></tr><tr><td colspan="4">Description: This effort will develop a prototype predictive tool that can provide the unit leader an indication of whether a potential mild traumatic brain injury event has occurred. This capability will provide the unit leader an additional objective tool to determine whether a Soldier can be safely exposed to more impacts without increased risk of injury.</td></tr><tr><td colspan="4">FY 2020 Plans: Will support the Environmental Sensors in Training (ESiT) program. Will support additional sites for data collection in high risk exposure communities: blast (heavy weapons training, breaching) and head impact (airborne).</td></tr><tr><td colspan="4">FY 2019 to FY 2020 Increase/Decrease Statement:</td></tr></table>														FY 2018	FY 2019	FY 2020	Title: Blast & Head Impact Exposure Monitor	-	-	1.412	Description: This effort will develop a prototype predictive tool that can provide the unit leader an indication of whether a potential mild traumatic brain injury event has occurred. This capability will provide the unit leader an additional objective tool to determine whether a Soldier can be safely exposed to more impacts without increased risk of injury.				FY 2020 Plans: Will support the Environmental Sensors in Training (ESiT) program. Will support additional sites for data collection in high risk exposure communities: blast (heavy weapons training, breaching) and head impact (airborne).				FY 2019 to FY 2020 Increase/Decrease Statement:			
	FY 2018	FY 2019	FY 2020																													
Title: Blast & Head Impact Exposure Monitor	-	-	1.412																													
Description: This effort will develop a prototype predictive tool that can provide the unit leader an indication of whether a potential mild traumatic brain injury event has occurred. This capability will provide the unit leader an additional objective tool to determine whether a Soldier can be safely exposed to more impacts without increased risk of injury.																																
FY 2020 Plans: Will support the Environmental Sensors in Training (ESiT) program. Will support additional sites for data collection in high risk exposure communities: blast (heavy weapons training, breaching) and head impact (airborne).																																
FY 2019 to FY 2020 Increase/Decrease Statement:																																

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2020 Army		<b>Date:</b> March 2019	
<b>Appropriation/Budget Activity</b> 2040 / 3	<b>R-1 Program Element (Number/Name)</b> PE 0603002A / <i>Medical Advanced Technology</i>	<b>Project (Number/Name)</b> MN6 / <i>Blast &amp; Head Impact Exposure Monitor Advanced Tech</i>	
<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>		<b>FY 2018</b>	<b>FY 2019</b>
Ongoing work realigned from other project due to S&T Financial Restructuring.			
<b>Accomplishments/Planned Programs Subtotals</b>		-	1.412
<b>C. Other Program Funding Summary (\$ in Millions)</b> N/A			
<b>Remarks</b>			
<b>D. Acquisition Strategy</b> N/A			
<b>E. Performance Metrics</b> N/A			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Army										Date: March 2019		
Appropriation/Budget Activity 2040 / 3					R-1 Program Element (Number/Name) PE 0603002A / Medical Advanced Technology				Project (Number/Name) MN7 / Musculoskeletal Injury Screening Tool Adv Tech			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
MN7: Musculoskeletal Injury Screening Tool Adv Tech	-	0.000	0.000	0.300	-	0.300	0.300	0.300	0.300	0.297	0.000	1.497
Note In Fiscal Year (FY) 2020 this Project was realigned from: Program Element (PE) 0603002A Medical Advanced Technology * Project MM3 Warfighter Medical Protection & Performance												
A. Mission Description and Budget Item Justification This capability will deliver a prototype unit leader tool that can assess the integrity of musculoskeletal tissue and provide an objective risk assessment for fitness for return to duty.  The cited work is fully coordinated with Natick Soldier Research Development (NSRDEC), Natick, MA and with other Services in order to avoid duplication of effort.  The cited work is consistent with the Under Secretary of Defense (Research and Engineering) science and technology focus areas and the Army Modernization Strategy. All FY 2020 adjustments align program resources to Army Modernization Priorities in support of the National Defense Strategy.  Work in this Project is performed by: the U.S. Army Medical Research Materiel Command (USAMRMC), Fort Detrick, MD.												
B. Accomplishments/Planned Programs (\$ in Millions)									FY 2018	FY 2019	FY 2020	
Title: Musculoskeletal Injury Screening Tool									-	-	0.300	
Description: This capability will deliver a prototype unit leader tool that can provide an objective assessment of musculoskeletal tissue integrity and provide fitness or return-to-duty recommendations.												
FY 2020 Plans: Will develop objective medical assessments of Return-to-Duty. Will support data collection in support of Training and Doctrine Command ? Center for Initial Military Training (TRADOC-CIMT)-led effort.												
FY 2019 to FY 2020 Increase/Decrease Statement: Ongoing work realigned from other project due to S&T Financial Restructuring.												
Accomplishments/Planned Programs Subtotals									-	-	0.300	

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Army		Date: March 2019
Appropriation/Budget Activity 2040 / 3	R-1 Program Element (Number/Name) PE 0603002A / Medical Advanced Technology	Project (Number/Name) MN7 / Musculoskeletal Injury Screening Tool Adv Tech
C. Other Program Funding Summary (\$ in Millions) N/A		
Remarks		
D. Acquisition Strategy N/A		
E. Performance Metrics N/A		

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Army										Date: March 2019			
Appropriation/Budget Activity 2040 / 3					R-1 Program Element (Number/Name) PE 0603002A / Medical Advanced Technology				Project (Number/Name) MN8 / Drugs to Prevent and Treat Malaria Advanced Tech				
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost	
MN8: Drugs to Prevent and Treat Malaria Advanced Tech	-	0.000	0.000	2.146	-	2.146	3.015	2.995	0.000	0.000	0.000	8.156	
Note In Fiscal Year (FY) 2020 this Project was realigned from: Program Element (PE) 0603002A Medical Advanced Technology * Project 810 Ind Base Id Vacc & Drug													
A. Mission Description and Budget Item Justification This Project covers technology development, demonstration, and transition of a candidate malaria prevention drug with weekly or less frequent dosing. The candidate drug may also be effective for the treatment of P. falciparum and P. vivax malaria. Infectious disease prevention sustains individual and unit readiness and reduces health services requirements and cost. Research is conducted in compliance with FDA regulations for medical products for human use.  Work is managed by the United States (U.S.) Army Medical Research and Materiel Command (USAMRMC) in coordination with the Naval Medical Research Center (NMRC). The Army is responsible for programming and funding all Department of Defense (DoD) naturally occurring infectious disease research requirements, thereby precluding duplication of effort within the Military Departments.  Promising medical countermeasures identified in this Project are further matured under PE 0603807A, Project 808.  The cited work is consistent with the Under Secretary of Defense (Research and Engineering) science and technology focus areas and the Army Modernization Strategy. All FY 2020 adjustments align program resources to Army Modernization Priorities in support of the National Defense Strategy.  Work in this Project is performed by: the U.S. Army Medical Research Materiel Command (USAMRMC), Fort Detrick, MD.  Efforts in this Project support the Soldier portfolio and the principal area of Military Relevant Infectious Diseases.													
B. Accomplishments/Planned Programs (\$ in Millions)									FY 2018	FY 2019	FY 2020		
Title: Drugs to Prevent and Treat Malaria Advanced Technology									-	-	2.146		
Description: Test drugs in healthy volunteers to determine drug pharmacology, safety, and effectiveness against malaria. Transition current lead anti-malarial prophylactic drug (triazine) with improved safety, effectiveness, and requiring less frequent dosing to PM Pharm in support of future FDA licensure.													
FY 2020 Plans:													

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2020 Army		<b>Date:</b> March 2019	
<b>Appropriation/Budget Activity</b> 2040 / 3	<b>R-1 Program Element (Number/Name)</b> PE 0603002A / <i>Medical Advanced Technology</i>	<b>Project (Number/Name)</b> MN8 / <i>Drugs to Prevent and Treat Malaria Advanced Tech</i>	
<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>		<b>FY 2018</b>	<b>FY 2019</b>
<p>Will complete clinical trial study data analysis then identify a single lead for use in humans. Will optimize lead formulation and test safety and toxicity in animals. Will initiate activities to perform a clinical trial in a small number of healthy human volunteers to test drug safety and effectiveness against P. falciparum malaria using controlled human malaria infection.</p> <p><b><i>FY 2019 to FY 2020 Increase/Decrease Statement:</i></b>  Funds for ongoing work were realigned to this project from Advanced Technology Research on drugs and vaccines against parasitic diseases</p>			
<b>Accomplishments/Planned Programs Subtotals</b>		-	-
<b>C. Other Program Funding Summary (\$ in Millions)</b>			
N/A			
<b>Remarks</b>			
<b>D. Acquisition Strategy</b>			
N/A			
<b>E. Performance Metrics</b>			
N/A			

# UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2020 Army										Date: March 2019			
Appropriation/Budget Activity 2040 / 3					R-1 Program Element (Number/Name) PE 0603002A / Medical Advanced Technology				Project (Number/Name) MN9 / Far Forward Behavioral Health Care Advanced Tech				
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost	
MN9: Far Forward Behavioral Health Care Advanced Tech	-	0.000	0.000	0.266	-	0.266	0.272	0.278	0.285	0.000	0.000	1.101	
Note In Fiscal Year (FY) 2020 this Project was realigned from: Program Element (PE) 0603002A Medical Advanced Technology * Project MM3 Warfighter Medical Protection & Performance													
A. Mission Description and Budget Item Justification This Project will deliver improved psychological treatment interventions to keep Soldiers in the fight under high intensity operational stressors.  The cited work is fully coordinated with Natick Soldier Research Development (NSRDEC), Natick, MA and with other Services in order to avoid duplication of effort.  The cited work is consistent with the Under Secretary of Defense (Research and Engineering) science and technology focus areas and the Army Modernization Strategy. All FY 2020 adjustments align program resources to Army Modernization Priorities in support of the National Defense Strategy.  Work in this Project is performed by: the U.S. Army Medical Research Materiel Command (USAMRMC), Fort Detrick, MD.													
B. Accomplishments/Planned Programs (\$ in Millions)									FY 2018	FY 2019	FY 2020		
Title: Optimal Delivery of Far Forward Behavioral Health Care									-	-	0.266		
Description: The effort will deliver improved psychological treatment interventions to keep Soldiers in the fight under high intensity operational stressors.													
FY 2020 Plans: The most promising brief psychotherapy interventions, self-administered computer apps, and treatment protocols for use with Service members deployed far forward will be identified and adapted and ready for initial clinical trials. An FDA-approved drug will also be under clinical trial evaluation for use to address Service member?s sleep problems in a far-forward setting for improved physical and psychological readiness and performance.													
FY 2019 to FY 2020 Increase/Decrease Statement: Ongoing work realigned from other project due to S&T Financial Restructuring.													
Accomplishments/Planned Programs Subtotals									-	-	0.266		

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Army		Date: March 2019
Appropriation/Budget Activity 2040 / 3	R-1 Program Element (Number/Name) PE 0603002A / Medical Advanced Technology	Project (Number/Name) MN9 / Far Forward Behavioral Health Care Advanced Tech
C. Other Program Funding Summary (\$ in Millions) N/A		
Remarks		
D. Acquisition Strategy N/A		
E. Performance Metrics N/A		



# UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2020 Army										Date: March 2019		
Appropriation/Budget Activity 2040 / 3					R-1 Program Element (Number/Name) PE 0603002A / Medical Advanced Technology				Project (Number/Name) MO2 / Traumatic Brain Injury (TBI) Treatment Adv Tech			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
MO2: Traumatic Brain Injury (TBI) Treatment Adv Tech	-	0.000	0.000	4.285	-	4.285	4.406	4.387	4.083	0.797	0.000	17.958
Note In Fiscal Year (FY) 2020 this Project was realigned from: Program Element (PE) 0603002A Medical Advanced Technology * Project 840 Combat Injury Mgmt												
A. Mission Description and Budget Item Justification This Project covers development, demonstration, and transition of technologies for acute battlefield management of Traumatic Brain Injury (TBI). Efforts include pre-clinical demonstration of drug therapy and resuscitation strategies for treatment of acute TBI in the pre-hospital setting, biomarkers, diagnostics, and devices, as well as novel drug delivery technologies to facilitate administration of pharmaceuticals at or near the point of injury to protect the injured brain from further damage.  All research is conducted in compliance with Food and Drug Administration (FDA) requirements for licensure of medical products for human use.  Promising efforts identified through Applied Research conducted under PE 0602787A, Project MM4 are further matured under this Project. Promising results identified under this Project are further matured under PE 0603807A, Project 836.  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 U.S. Army Medical Research Materiel Command (USAMRMC), Fort Detrick, MD..												
B. Accomplishments/Planned Programs (\$ in Millions)									FY 2018	FY 2019	FY 2020	
Title: Selective Brain Cooling and Stem Cell Therapeutic Product Candidates for TBI									-	-	4.285	
Description: Development, demonstration, and transition of technologies to treat TBI. Preclinical demonstration of stem cell transplantation to repair and regenerate the injured brain. Preclinical demonstration of a candidate selective brain-cooling device that protects the brain and reduces death from severe TBI but without adverse effects from whole-body cooling.												
FY 2020 Plans:												

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2020 Army		<b>Date:</b> March 2019	
<b>Appropriation/Budget Activity</b> 2040 / 3	<b>R-1 Program Element (Number/Name)</b> PE 0603002A / <i>Medical Advanced Technology</i>	<b>Project (Number/Name)</b> MO2 / <i>Traumatic Brain Injury (TBI) Treatment Adv Tech</i>	
<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>		<b>FY 2018</b>	<b>FY 2019</b>
Will demonstrate stem cell transplantation as a strategy to repair and regenerate the injured brain. Will have preclinical demonstration of a device that provides selective cooling of the brain, to protect the brain and reduce mortality in severe TBI while preventing the secondary adverse effects associated with whole body cooling.			
<b>FY 2019 to FY 2020 Increase/Decrease Statement:</b> Funds for ongoing work were realigned from Project 840 / Traumatic Brain Injury (TBI)			
<b>Accomplishments/Planned Programs Subtotals</b>		-	4.285
<b>C. Other Program Funding Summary (\$ in Millions)</b> N/A			
<b>Remarks</b>			
<b>D. Acquisition Strategy</b> N/A			
<b>E. Performance Metrics</b> N/A			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Army										Date: March 2019		
Appropriation/Budget Activity 2040 / 3					R-1 Program Element (Number/Name) PE 0603002A / Medical Advanced Technology				Project (Number/Name) MO3 / Military Occupational Fitness Standards Adv Tech			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
MO3: Military Occupational Fitness Standards Adv Tech	-	0.000	0.000	0.250	-	0.250	0.300	0.300	0.150	0.000	0.000	1.000
Note In Fiscal Year (FY) 2020 this Project was realigned from: Program Element (PE) 0603002A Medical Advanced Technology * Project MM3 Warfighter Medical Protection & Performance												
A. Mission Description and Budget Item Justification This capability will provide the unit leader a validated toolkit of operationally relevant physical fitness assessments that can supplement clinical criteria to determine whether a Soldier can return to duty after musculoskeletal injury without the risk of re-injury.  The cited work is fully coordinated with Natick Soldier Research Development (NSRDEC), Natick, MA and with other Services in order to avoid duplication of effort.  The cited work is consistent with the Under Secretary of Defense (Research and Engineering) science and technology focus areas and the Army Modernization Strategy. All FY20 adjustments align program resources to Army Modernization Priorities in support of the National Defense Strategy.  Work in this Project is performed by: the U.S. Army Medical Research Materiel Command (USAMRMC), Fort Detrick, MD.												
B. Accomplishments/Planned Programs (\$ in Millions)									FY 2018	FY 2019	FY 2020	
Title: Military Occupational Fitness Standards									-	-	0.250	
Description: This capability will provide the unit leader a validated toolkit of operationally relevant physical fitness assessments that can supplement clinical criteria to determine whether a Soldier can return to duty after musculoskeletal injury without the risk of re-injury.  FY 2020 Plans: Will validate physical fitness standards and Return-to-Duty strategies, including the validation of Return-to-Duty during basic combat training.  FY 2019 to FY 2020 Increase/Decrease Statement: Ongoing work realigned from other project due to S&T Financial Restructuring.												
Accomplishments/Planned Programs Subtotals									-	-	0.250	

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Army		Date: March 2019
Appropriation/Budget Activity 2040 / 3	R-1 Program Element (Number/Name) PE 0603002A / Medical Advanced Technology	Project (Number/Name) MO3 / Military Occupational Fitness Standards Adv Tech
C. Other Program Funding Summary (\$ in Millions) N/A		
Remarks		
D. Acquisition Strategy N/A		
E. Performance Metrics N/A		

# UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2020 Army										Date: March 2019		
Appropriation/Budget Activity 2040 / 3					R-1 Program Element (Number/Name) PE 0603002A / Medical Advanced Technology				Project (Number/Name) MO4 / Burn Recovery Optimization Advanced Technology			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
MO4: Burn Recovery Optimization Advanced Technology	-	0.000	0.000	2.084	-	2.084	3.297	5.500	5.434	5.099	0.000	21.414
<b>Note</b> In Fiscal Year (FY) 2020 this Project was realigned from: Program Element (PE) 0603002A Medical Advanced Technology * Project 840 Combat Injury Mgmt												
<b>A. Mission Description and Budget Item Justification</b> This Project covers technology development, demonstration, and transition of burn recovery optimization technologies, including: diagnostic technology to predict skin graft success or failure and identify patients at heightened risk for scarring; and adult stem cell therapy candidate to decrease inflammation and limit organ injury following severe burns.  All research is conducted in compliance with Food and Drug Administration (FDA) requirements for licensure of medical products for human use.  Promising efforts identified through Applied Research conducted under PE 0602787A, Project MM4 are further matured under this Project. Promising results identified under this Project are further matured under PE 0603807A, Project 836.  The cited work is consistent with the Under Secretary of Defense (Research and Engineering) science and technology focus areas and the Army Modernization Strategy. All FY 2020 adjustments align program resources to Army Modernization Priorities in support of the National Defense Strategy.  Work in this Project is performed by: the U.S. Army Medical Research Materiel Command (USAMRMC), Fort Detrick, MD.												
<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>									FY 2018	FY 2019	FY 2020	
<b>Title:</b> Theranostic Product Candidates to Optimize Burn Recovery									-	-	2.084	
<b>Description:</b> Technology development, demonstration, and transition of burn recovery optimization technologies: diagnostic technology to predict skin graft success or failure and identify patients at heightened risk for scarring; adult stem cell therapy candidate to decrease inflammation and limit organ injury following severe burns.												
<b>FY 2020 Plans:</b> Will demonstrate biomarkers to identify skin graft success or failure, and to identify which patients are at heightened risk for scarring. Will develop and demonstrate treatments using mesenchymal stem cells (these are human cells that can, under the												

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2020 Army		<b>Date:</b> March 2019	
<b>Appropriation/Budget Activity</b> 2040 / 3	<b>R-1 Program Element (Number/Name)</b> PE 0603002A / <i>Medical Advanced Technology</i>	<b>Project (Number/Name)</b> MO4 / <i>Burn Recovery Optimization Advanced Technology</i>	
<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>		<b>FY 2018</b>	<b>FY 2019</b>
right conditions, transform into multiple cell types having ability to repair damaged tissue) to decrease inflammation and limit systemic organ injury following severe burn injury.			
<b>FY 2019 to FY 2020 Increase/Decrease Statement:</b> Funds for ongoing work were realigned from Project 840 / Combat Trauma Therapies			
<b>Accomplishments/Planned Programs Subtotals</b>		-	2.084
<b>C. Other Program Funding Summary (\$ in Millions)</b> N/A			
<b>Remarks</b>			
<b>D. Acquisition Strategy</b> N/A			
<b>E. Performance Metrics</b> N/A			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Army									Date: March 2019				
Appropriation/Budget Activity 2040 / 3					R-1 Program Element (Number/Name) PE 0603002A / Medical Advanced Technology				Project (Number/Name) MO7 / Improved Bone Repair Advanced Technology				
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost	
MOT: Improved Bone Repair Advanced Technology	-	0.000	0.000	1.539	-	1.539	1.369	1.230	1.303	1.344	0.000	6.785	
Note In Fiscal Year (FY) 2020 this Project was realigned from: Program Element (PE) 0603002A Medical Advanced Technology * Project 840 Combat Injury Mgmt													
A. Mission Description and Budget Item Justification This Project covers development, demonstration, and transition of technologies that improve outcomes following severe limb injuries to include open bone fractures and all related acute and prolonged field care complications of severe limb trauma.  All research is conducted in compliance with Food and Drug Administration (FDA) requirements for licensure of medical products for human use.  Promising efforts identified through Applied Research conducted under PE 0602787A, Project MM4 are further matured under this Project. Promising results identified under this Project are further matured under PE 0603807A, Project 836.  The cited work is consistent with the Under Secretary of Defense (Research and Engineering) science and technology focus areas and the Army Modernization Strategy. All FY 2020 adjustments align program resources to Army Modernization Priorities in support of the National Defense Strategy.  Work in this Project is performed by: the U.S. Army Medical Research Materiel Command (USAMRMC), Fort Detrick, MD.													
B. Accomplishments/Planned Programs (\$ in Millions)									FY 2018	FY 2019	FY 2020		
Title: Technology Candidates for Stabilization and Treatment of Extremity Trauma									-	-	1.539		
Description: Development, demonstration, and transition of technologies that improve bone repair outcomes in severe limb injuries where the two ends of a broken bone cannot be rejoined (for example, because part of the bone is missing, or the fracture is contaminated with bacteria, which inhibits normal healing).													
FY 2020 Plans: Will develop technologies to repair deleterious complications that prevent bone union and healing in severe extremity fractures.													
FY 2019 to FY 2020 Increase/Decrease Statement:													

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2020 Army		<b>Date:</b> March 2019	
<b>Appropriation/Budget Activity</b> 2040 / 3	<b>R-1 Program Element (Number/Name)</b> PE 0603002A / <i>Medical Advanced Technology</i>	<b>Project (Number/Name)</b> MO7 / <i>Improved Bone Repair Advanced Technology</i>	

  

<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>
Funds for ongoing work were realigned from Project 840 / Combat Trauma Therapies			
<b>Accomplishments/Planned Programs Subtotals</b>	-	-	1.539

  

**C. Other Program Funding Summary (\$ in Millions)**  
N/A

**Remarks**

**D. Acquisition Strategy**  
N/A

**E. Performance Metrics**  
N/A



# UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2020 Army										Date: March 2019		
Appropriation/Budget Activity 2040 / 3					R-1 Program Element (Number/Name) PE 0603002A / Medical Advanced Technology				Project (Number/Name) MO8 / Expeditionary Performance Nutrition Advanced Techn			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
MO8: Expeditionary Performance Nutrition Advanced Techn	-	0.000	0.000	0.200	-	0.200	0.429	0.511	0.520	0.476	0.000	2.136
Note In Fiscal Year (FY) 2020 this Project was realigned from: Program Element (PE) 0603002A Medical Advanced Technology * Project MM3 Warfighter Medical Protection & Performance												
A. Mission Description and Budget Item Justification This Project covers development of nutritionally-optimized food products that will be matured to allow a soldier to eat-on-the-go while ensuring maximal physiological and cognitive performance with minimal logistical footprint.  The cited work is fully coordinated with Natick Soldier Research Development (NSRDEC), Natick, MA and with other Services in order to avoid duplication of effort.  The cited work is consistent with the Under Secretary of Defense (Research and Engineering) science and technology focus areas and the Army Modernization Strategy. All FY 2020 adjustments align program resources to Army Modernization Priorities in support of the National Defense Strategy.  Work in this Project is performed by: the U.S. Army Medical Research Materiel Command (USAMRMC), Fort Detrick, MD..												
B. Accomplishments/Planned Programs (\$ in Millions)									FY 2018	FY 2019	FY 2020	
Title: Performance Nutrition for an Expeditionary Force									-	-	0.200	
Description: Development of nutritionally-optimized food products prototypes that will allow Soldiers to eat-on-the-go with minimal logistical footprint while ensuring maximal physiological and cognitive performance.												
FY 2020 Plans: Will evaluate and provide components of food prototypes that are nutritionally optimized for cognitive and physical performance, configured for eating-on-the-go and compatible with multiple ration platforms (e.g., Meal-Ready-to-Eat [MRE], First Strike Ration [FSR]), tailorable for mission requirements, e.g., high/low physical or cognitive demand, formulated to enhance immune function and promote readiness and lighter weight with reduced logistical footprint.												
FY 2019 to FY 2020 Increase/Decrease Statement:												

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Army		Date: March 2019	
Appropriation/Budget Activity 2040 / 3	R-1 Program Element (Number/Name) PE 0603002A / Medical Advanced Technology	Project (Number/Name) MO8 / Expeditionary Performance Nutrition Advanced Techn	
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2018	FY 2019
Ongoing work realigned from other project due to S&T Financial Restructuring.			
Accomplishments/Planned Programs Subtotals		-	0.200
C. Other Program Funding Summary (\$ in Millions)			
N/A			
Remarks			
D. Acquisition Strategy			
N/A			
E. Performance Metrics			
N/A			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Army										Date: March 2019		
Appropriation/Budget Activity 2040 / 3					R-1 Program Element (Number/Name) PE 0603002A / Medical Advanced Technology				Project (Number/Name) MO9 / Vaccines to Prevent Dengue Fever Advanced Tech			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
MO9: Vaccines to Prevent Dengue Fever Advanced Tech	-	0.000	0.000	2.533	-	2.533	2.434	2.399	2.713	2.736	0.000	12.815
Note In Fiscal Year (FY) 2020 this Project was realigned from: Program Element (PE) 0603002A Medical Advanced Technology * Project 810 Ind Base Id Vacc & Drug												
A. Mission Description and Budget Item Justification This Project covers technology development, demonstration, and transition of a candidate vaccine for the prevention of dengue hemorrhagic fever or dengue shock syndrome caused by any of the 4 dengue virus types. The vaccine will be effective in people with and without a prior history of dengue infection. Infectious disease prevention sustains individual and unit readiness and reduces health services requirements and cost.  Work in this Project is managed by the United States (U.S.) Army Medical Research and Materiel Command (USAMRMC) in coordination with the Naval Medical Research Center (NMRC). The Army is responsible for programming and funding all Department of Defense (DoD) naturally occurring infectious disease research requirements, thereby precluding duplication of effort within the Military Departments.  Promising medical countermeasures identified in this Project are further matured under PE 0603807A, Project 808.  The cited work is consistent with the Under Secretary of Defense (Research and Engineering) science and technology focus areas and the Army Modernization Strategy. All FY 2020 adjustments align program resources to Army Modernization Priorities in support of the National Defense Strategy.  Work in this Project is performed by USAMRMC at Fort Detrick, MD.  Efforts in this Project support the Soldier portfolio and the principal area of Military Relevant Infectious Diseases.												
B. Accomplishments/Planned Programs (\$ in Millions)									FY 2018	FY 2019	FY 2020	
Title: Vaccines to Prevent Dengue Fever Advanced Technology									-	-	2.533	
Description: Perform small studies in healthy volunteers to test vaccine safety, effectiveness, and immunogenicity against Dengue Fever. Transition vaccine with high effectiveness and safety against all four serotypes of Dengue to PM Pharm in support of future FDA licensure.												
FY 2020 Plans:												

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2020 Army		<b>Date:</b> March 2019	
<b>Appropriation/Budget Activity</b> 2040 / 3	<b>R-1 Program Element (Number/Name)</b> PE 0603002A / <i>Medical Advanced Technology</i>	<b>Project (Number/Name)</b> MO9 / <i>Vaccines to Prevent Dengue Fever Advanced Tech</i>	
<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>		<b>FY 2018</b>	<b>FY 2019</b>
Will perform clinical trial where optimized vaccine regimen is tested for safety and immunogenicity in humans. Will perform clinical trial to test for additional safety, immunogenicity and effectiveness against a Dengue challenge model against Dengue serotypes.			
<b><i>FY 2019 to FY 2020 Increase/Decrease Statement:</i></b> Funds for ongoing work were realigned to this project from Viral Disease Threats			
<b>Accomplishments/Planned Programs Subtotals</b>		-	2.533
<b>C. Other Program Funding Summary (\$ in Millions)</b> N/A			
<b>Remarks</b>			
<b>D. Acquisition Strategy</b> N/A			
<b>E. Performance Metrics</b> N/A			