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**Exhibit R-2, RDT&E Budget Item Justification:** PB 2024 Army **Date:** March 2023

<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 0603115A / <i>Medical Development</i>
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COST (\$ in Millions)	Prior Years	FY 2022	FY 2023	FY 2024 Base	FY 2024 OCO	FY 2024 Total	FY 2025	FY 2026	FY 2027	FY 2028	Cost To Complete	Total Cost
Total Program Element	0.000	25.540	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	25.540
EB3: <i>HIV Medical Development</i>	-	25.540	-	-	-	-	-	-	-	-	0.000	25.540

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

This Program Element (PE) funds the Military Human Immunodeficiency Virus (HIV) Research Program and the following medical research efforts: Walter Reed Army Institute of Research (WRAIR) Vaccine Production research, Underbody Blast (UBB) research, and Deployed Warfighter Protection. Funding also supports the Medical Operational Data System (MODS), Pharmacovigilance Defense Application System (PVDAS), Mobile HealthCare Environment (MHCE), and the Civilian Authorized Salaries and Other Operational Requirements programs.

The Military HIV Program supports the research and development to develop candidate HIV vaccines, to assess safety and effectiveness in human subjects and to protect military personnel from risks associated with HIV infection.

The WRAIR Vaccine Production Facility research Project supports the development and licensure of vaccines and relevant biologics critical to the global health of our Warfighters serving domestically or abroad in compliance with Food and Drug Administration (FDA) regulations.

The UBB Testing medical research Project provides funds to establish a scientific and statistical basis for evaluating skeletal injuries to vehicle occupants during ground vehicle UBB events. Areas of interest to the Secretary of Defense are medical research that provides an understanding of the human response and tolerance limits and injury mechanisms needed to accurately predict skeletal injuries to ground combat vehicle occupants caused by UBB events. This enhanced understanding will support the establishment of an improved capability to conduct Title 10 Live Fire Test and Evaluation and to make acquisition decisions.

The Deployed Warfighter Protection program Armed Forces Pest Management Board provides for the development of new or improved protection of military personnel from insects and tick vectors of disease pathogens.

The MODS, PPVDAS, and MHCE identify, explore and demonstrate key technologies to overcome medical and military unique technology barriers.

The Civilian Authorized Salaries and other operational requirements provide funding for authorized civilian workforce performing medical research, development, acquisition management and oversight that support the medical research, development, test, and evaluation (RDTE) programs at the United States Army Medical Research and Development Command (USAMRDC), Fort Detrick, Maryland.

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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 0603115A / <i>Medical Development</i>
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<b>B. Program Change Summary (\$ in Millions)</b>	<u>FY 2022</u>	<u>FY 2023</u>	<u>FY 2024 Base</u>	<u>FY 2024 OCO</u>	<u>FY 2024 Total</u>
Previous President's Budget	26.508	0.000	0.000	-	0.000
Current President's Budget	25.540	0.000	0.000	-	0.000
Total Adjustments	-0.968	0.000	0.000	-	0.000
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-0.968	-			
• SBIR/STTR Transfer	-	-			

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2024 Army										<b>Date:</b> March 2023		
<b>Appropriation/Budget Activity</b> 2040 / 3					<b>R-1 Program Element (Number/Name)</b> PE 0603115A / <i>Medical Development</i>				<b>Project (Number/Name)</b> EB3 / <i>HIV Medical Development</i>			
<b>COST (\$ in Millions)</b>	<b>Prior Years</b>	<b>FY 2022</b>	<b>FY 2023</b>	<b>FY 2024 Base</b>	<b>FY 2024 OCO</b>	<b>FY 2024 Total</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>	<b>FY 2028</b>	<b>Cost To Complete</b>	<b>Total Cost</b>
EB3: <i>HIV Medical Development</i>	-	25.540	-	-	-	-	-	-	-	-	0.000	25.540
Quantity of RDT&E Articles	-	-	-	-	-	-	-	-	-	-		

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

The Military Human Immunodeficiency Virus (HIV) Research Program develops vaccine candidates, to assess their safety and effectiveness in human subjects, and to protect military personnel from risks associated with HIV infection. All HIV technology development is conducted in compliance with United States Food and Drug Administration (FDA) regulations. This program is jointly managed through an Interagency Agreement between the United States Army Medical Research and Development Command (USAMRDC) and the National Institute of Allergy and Infectious Diseases. The cited work is also consistent with the Under Secretary of Defense, Research and Engineering Science and Technology focus areas.

The Walter Reed Army Institute of Research (WRAIR) Vaccine Pilot Bioproduction Facility (PBF) is the Department of Defense (DOD) only facility capable of producing good manufacturing practices (GMP) quality biologic products for use in early phase clinical trials. The mission of the WRAIR PBF is to support the development and licensure of vaccines and relevant biologics critical to the global health of our Warfighters serving domestically or abroad in compliance with United States FDA regulations. This project supports vaccine development efforts of strategic importance to the DoD, including Service medical research and development programs, those of other DoD organization such as the Defense Threat Reduction Agency and the Defense Advanced Research Projects Agency, and pandemic bio preparedness for emerging infectious disease threats in the Global Health Security Agenda.

The Underbody Blast (UBB) Testing medical research project will provide new data on the biomechanics of human skeletal response that occurs in an attack on a ground combat vehicle, it will provide better protection to mounted warriors from the effects of underbody blast caused by landmines or improvised explosive devices (IEDs). The data will provide a biomedical basis for the development of a Warrior-representative blast test manikin (the Warrior Injury Assessment Manikin or WIAMan project) and the required biomedically-valid injury criteria that can be used in Title 10 Live Fire Test and Evaluation (LFT&E) to characterize dynamic events, the risk of injury to mounted warriors, and to support acquisition decisions. The data produced by this project will be used to satisfy a critical need for a scientifically valid capability for analyzing the risk of injury caused by UBB.

The Deployed Warfighter Protection project, the Armed Forces Pest Management Board (AFPMB), plans to develop new or improved protection for ground forces from disease-carrying insects. The focus of this program is to develop new or improved systems for controlling insects that transmit malaria, dengue, chikungunya and other emerging infectious diseases under austere, remote, and combat conditions; understand the physiology of insecticidal activity to develop new compounds with greater specific activity and/or higher user acceptability; examine existing area repellents for efficacy and develop new spatially effective repellent systems useful in military situations; develop new methods or formulations for treating cloth to prevent vector biting; and expand the number of active ingredients and formulations of public health pest pesticides, products and application technologies available for safe, and effective applications. The AFPMB partners with the President's Malaria Initiative and the World Health Organization Global Malaria Program to lead development of new tools for insect-borne disease prevention.

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The Medical Operational Data System (MODS) deploys modernized data visualization capabilities to enhance Army Unit and Individual Medical Readiness Reporting. MODS provides Army leadership with a responsive and reliable human resource and readiness information management data system for all categories of military and civilian medical and support personnel. MODS provide Tri-Service support through applications such as Electronic Profile, Behavioral Health, and Medical Education.

The Pharmacovigilance Defense Application System (PVDAS) provides military providers Defense Patient Safety reports from the FDA after a drug's release to market. The program identifies, explores, and demonstrates key information technologies to overcome medical and military unique technology barriers.

The Mobile HealthCare Environment (MHCE) is the capability of secure, bidirectional messaging and data exchange between patients, providers and clinics using any electronic device. The program identifies, explores, and demonstrates key information technologies to overcome medical and military unique technology barriers.

The Civilian Authorized Salaries and Other Operational requirements provide funding for authorized civilian workforce performing medical research, development, acquisition management and oversight that support the medical research, development, test, and evaluation (RDTE) programs at the United States Army Medical Research and Development Command (USAMRDC), Fort Detrick, Maryland.

<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>	<b>FY 2022</b>	<b>FY 2023</b>	<b>FY 2024</b>
<p><b>Title:</b> HIV Medical Development</p> <p><b>Description:</b> The Military HIV Research Program aims to mature candidate HIV vaccines, to validate their safety and effectiveness in human subjects, and to protect the military personnel from risks associated with HIV infection. These activities also include development of monoclonal antibody candidates to address HIV risk to the blood supply in large scale combat operations This project determines one or more prevention countermeasure candidates that are optimized through pre-clinical down-selection studies in large animal models and conducts human clinical trials in Africa, Asia and the United States to test for safety and immunogenicity (ability to invoke an immune response), and contributes to early proof of concept efficacy testing.</p>	7.833	-	-
<p><b>Title:</b> WRAIR Vaccine Production Facility Research</p> <p><b>Description:</b> The WRAIR Vaccine Pilot Bioproduction Facility (PBF) will focus on advanced technology development and transition through production of early phase (1/2a) clinical materials from varied platforms, such as live virus, conjugates, recombinant proteins, monoclonal antibodies, Ribonucleic Acid (RNA) and deoxyribonucleic acid (DNA) approaches that: (a) expand collaborative partnerships for product development that meet DoD requirements; (b) open active intramural-based discovery efforts of new products for development; and (c) initiate and extend strategic partnerships with external collaborators (Government and industry) to develop/co-develop potential new biologic approaches to pandemic disease preparedness.</p>	8.107	-	-
<p><b>Title:</b> Deployed Warfighter Protection</p> <p><b>Description:</b> The Deployed Warfighter Protection program will mature new or improved tools to protect deployed forces from disease-carrying insects and ticks.</p>	6.303	-	-
<p><b>Title:</b> Medical Operational Data System</p>	1.909	-	-

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<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>	FY 2022	FY 2023	FY 2024
<p><b>Description:</b> The Medical Operational Data System is the Army's authoritative data source for Individual Medical Readiness (IMR) reporting, and supports Army Global Medical Force Readiness (GMFR) to include the Army Surgeon General Title X responsibilities to recruit, retain, pay and train the Army Medical Force.</p>			
<p><b>Title:</b> Pharmacovigilance Defense Application System</p> <p><b>Description:</b> The PVDAS provides military providers Defense Patient Safety reports from the FDA after a drug's release to market.</p>	0.304	-	-
<p><b>Title:</b> Mobile Health Care Environment</p> <p><b>Description:</b> The Mobile HealthCare Environment matures and demonstrates technologies to support the capability of secure, bidirectional messaging and data exchange between patients, providers and clinics using any electronic device.</p>	0.331	-	-
<p><b>Title:</b> Civilian Authorized Salaries and Other Operational Requirements</p> <p><b>Description:</b> Funding is provided to the USAMRDC for Medical Research Development Acquisition (RDA) Management and Oversight to include the payroll of civilians as well as nominal operating expense</p>	0.753	-	-
<b>Accomplishments/Planned Programs Subtotals</b>	25.540	-	-

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

N/A

**Remarks**

**D. Acquisition Strategy**

N/A