Exhibit R-2, RDT&E Budget Item Justification: PB 2022 Army												Date: May 2021
Appropriation/Budget Activity 2040: *Research, Development, Test & Evaluation, Army I* BA 3: *Advanced Technology Development (ATD)*					R-1 Program Element (Number/Name) PE 0603115A *I Medical Development*							
COST ($ in Millions)	**Prior Years**	**FY 2020**	**FY 2021**	**FY 2022 Base**	**FY 2022 OCO**	**FY 2022 Total**	**FY 2023**	**FY 2024**	**FY 2025**	**FY 2026**	**Cost To Complete**	**Total Cost**
Total Program Element	-	-	26.711	26.521	-	26.521	-	-	-	-	-	-
EB3: *HIV Medical Development*	-	-	26.711	26.521	-	26.521	-	-	-	-	-	-

A. Mission Description and Budget Item Justification

This 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 US Food and Drug Administration (FDA) regulations.

The Underbody Blast (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 Medical Operational Data System (MODS), Pharmacovigilance Defense Application System (PVDAS), and Mobile HealthCare Environment (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.

In FY21 programs these programs were transferred from the Defense Health Agency (DHA) to the United States Army.

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Appropriation/Budget Activity 2040: *Research, Development, Test & Evaluation, Army I* BA 3: *Advanced Technology Development (ATD)*			R-1 Program Element (Number/Name) PE 0603115A *I Medical Development*		
B. Program Change Summary ($ in Millions)	**FY 2020**	**FY 2021**	**FY 2022 Base**	**FY 2022 OCO**	**FY 2022 Total**
Previous President's Budget	0.000	27.723	26.849	-	26.849
Current President's Budget	0.000	26.711	26.521	-	26.521
Total Adjustments	0.000	-1.012	-0.328	-	-0.328
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-	-1.012			
• Adjustments to Budget Years	-	-	-0.328	-	-0.328

Exhibit R-2A, RDT&E Project Justification: PB 2022 Army			Date: May 2021
Appropriation/Budget Activity 2040 / 3	R-1 Program Element (Number/Name) PE 0603115A / *Medical Development*	Project (Number/Name) EB3 / *HIV Medical Development*	

COST ($ in Millions)	Prior Years	FY 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	FY 2023	FY 2024	FY 2025	FY 2026	Cost To Complete	Total Cost
EB3: *HIV Medical Development*	-	-	26.711	26.521	-	26.521	-	-	-	-	-	-
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 Assistant 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 Food and Drug Administration (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. Accomplishments/Planned Programs ($ in Millions)	FY 2020	FY 2021	FY 2022
Title: HIV Medical Development	-	7.909	8.134
Description: 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. In addition, program also aims to develop other prevention and treatment strategies to mitigate the HIV epidemic globally. This project determines one or more vaccine 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 early proof of concept efficacy testing.			
FY 2021 Plans: The Military HIV research program continues Early Capture HIV Cohort studies in Europe and Asia with the purpose of characterizing recruitment, retention, HIV prevalence, HIV incidence and biological characteristics of acute HIV infection in high risk volunteers. Human population studies in Asia, Europe and West Africa will continue to provide knowledge about the earliest HIV events to inform vaccine development. Human clinical trials in Africa, Asia and the United States designed to test for safety, immunogenicity and early proof of concept efficacy of candidate vaccines will continue.			
FY 2022 Plans: Military Health Research Program will complete a human trial evaluating multi-dose vaccine regimens with the optimized dose of the Army?s lead adjuvant, determining a lead protein boost vaccine candidate for further development; determine whether rapid administration of vaccines can elicit stronger antibody responses; determine which formulations of the leading Army adjuvant			

Exhibit R-2A, RDT&E Project Justification: PB 2022 Army		Date: May 2021
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B. Accomplishments/Planned Programs ($ in Millions)	FY 2020	FY 2021	FY 2022
are the best for safety, immune responses and manufacturing; demonstrate Good Manufacturing Practice manufacture of next generation subtype B mosaic vaccine candidates, informed by results from trials in large animal models. ***FY 2021 to FY 2022 Increase/Decrease Statement:*** Funding change reflects planned lifecycle of this effort.			
Title: WRAIR Vaccine Production Facility Research ***Description:*** The WRAIR Vaccine Pilot Bioproduction Facility 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, RNA and 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. ***FY 2021 Plans:*** The WRAIR PBF program continues vaccine and biologic production efforts for use in early phase clinical trials to assess safety and effectiveness of candidate vaccines. ***FY 2022 Plans:*** The WRAIR Pilot Bioproduction Facility is a support function for novel S&T programs from across MRDC and the DoD to advance the development of vaccine products into early phase (1/2a) clinical trials. Following full operational capability establishment in FY21 the PBF will focus on fostering partnerships with both internal and external stakeholders to continue vaccine and biologic production efforts to support transfer of 6.1-6.3 activities for DoD and external stakeholders. These efforts will align to the technology maturation and risk reduction of medical countermeasures for through early phase (1/2a) clinical trials to assess safety and effectiveness of candidate vaccines to support the warfighter. ***FY 2021 to FY 2022 Increase/Decrease Statement:*** Funding change reflects planned lifecycle of this effort.	-	8.189	8.417
Title: Underbody Blast Testing ***Description:*** The Under Body Blast (UBB) Testing will provide an understanding of the biomechanics of skeletal injuries that occur in a combat vehicle UBB event involving a landmine or improvised explosive device (IED), and the biomedical basis for the development of a Warrior-representative blast test manikin and associated biomedically-validated injury criteria that can be used to characterize dynamic events and injury risks for LFT&E crew survivability assessments and vehicle development efforts to better protect Warriors from UBB threats. ***FY 2021 Plans:***	-	1.274	-

Exhibit R-2A, RDT&E Project Justification: PB 2022 Army		Date: May 2021
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B. Accomplishments/Planned Programs ($ in Millions)	FY 2020	FY 2021	FY 2022
The Underbody Blast Testing program prepares final reports and complete contract closeouts to support completion of program efforts. ***FY 2021 to FY 2022 Increase/Decrease Statement:*** Project ended in FY21.			
Title: Deployed Warfighter Protection ***Description:*** The Deployed Warfighter Protection program will mature new or improved protection for ground forces from disease carrying insects and ticks. ***FY 2021 Plans:*** The Deployed Warfighter Protection research project continues to conduct translational research to develop and field tools that protect against emerging infectious disease threats and enable deployed forces to enhance protection from biting insects, primarily mosquitoes and sand flies, which transmit force degrading diseases. The AFPMB Vector Control Capabilities Gap Analysis (completed in FY 2016) continues to be used to inform the development of functional and performance requirements for future acquisition programs. In addition, the AFPMB continues to develop the necessary test and evaluation plans to determine a candidate product's ability to meet its stated requirements. ***FY 2022 Plans:*** The Deployed Warfighter Protection program continues early translational research for the development of novel tools that protect deployed forces from biting ticks, mosquitoes and other insects which transmit lethal and force degrading diseases. The Armed Forces Pest Management Board (AFPMB) continues to inform the development of performance requirements and necessary test and evaluation plans to determine a candidate product's capabilities and limitations. Novel vector control capabilities (including RNAi insecticides targeting specific vector species) and personal bite protection tools (including new uniform fabric technologies and area repellents) will be developed for further testing in operationally relevant environments. ***FY 2021 to FY 2022 Increase/Decrease Statement:*** Funding change reflects planned lifecycle of this effort.	-	6.347	6.545
Title: Medical Operational Data System ***Description:*** 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. ***FY 2021 Plans:*** Medical Operational Data System responds to Milestone Decision Authority decisions to add new capabilities, significantly enhance, and technically upgrade existing capabilities, and use federally funded research and development center resources	-	1.868	1.983

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2020	FY 2021	FY 2022
for system engineering and acquisition effectiveness services. These technology upgrades support the system's ability to help strengthen the scientific basis for decision-making in patient safety and quality performance within the Military Health System. ***FY 2022 Plans:*** Medical Operational Data System (MODS) will complete the Engineering Process needed for required modifications to the MODS Medical Assembly Mobilization Planning Data Platform to support the Army's evolving business/operational requirements in support of Medical Readiness of the Force. ***FY 2021 to FY 2022 Increase/Decrease Statement:*** Funding change reflects planned lifecycle of this effort.			
Title: Pharmacovigilance Defense Application System ***Description:*** The Pharmacovigilance Defense Application System (PVDAS) provides military providers Defense Patient Safety reports from the Food and Drug Administration (FDA) after a drug's release to market. ***FY 2021 Plans:*** Pharmacovigilance Defense Application System implements the testing of the drug surveillance and data visualization capabilities that were developed during previous fiscal years. ***FY 2022 Plans:*** Pharmacovigilance Defense Application System will demonstrate modifications to directly access to military healthcare databases, thus eliminating the need for its own data warehouse, to give the application access to the most up-to-date information while also increasing capability and capacity to conduct drug studies and analyses. The results will optimize drug-use safety and improve prescribing practices in the Military Healthcare System (MHS) at reduced total cost of ownership (TCO). ***FY 2021 to FY 2022 Increase/Decrease Statement:*** No change.	-	0.224	0.316
Title: Mobile Health Care Environment ***Description:*** 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. ***FY 2021 Plans:*** The Mobile HealthCare Environment program finalizes its functionality expansion which will be the data exchange with other systems, specifically a patient's personal health record, and enterprise systems such as their electronic health record. These	-	0.238	0.344

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2020	FY 2021	FY 2022
system enhancements supports the Army's ability to help strengthen the scientific basis for decision-making in patient safety and quality performance within the Military Health System. ***FY 2022 Plans:*** Will continue device and data integration with backend records databases. Demand in these areas requires extensive requirements analysis, programming, and validation of secure chat, video and file sharing capabilities within the platform expansion completed for data integration. ***FY 2021 to FY 2022 Increase/Decrease Statement:*** Funding change reflects planned lifecycle of this effort.			
Title: Civilian Authorized Salaries and Other Operational Requirements ***Description:*** 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. ***FY 2021 Plans:*** Funds authorized civilian salaries and associated expenses (supplies, equipment, travel, etc.) at USAMRDC and United States Army Medical Research Acquisition Activity. Funding also provides regulatory, clinical monitoring and data support for the Special Immunization Program. This program provides non-licensed vaccines under FDA oversight to personnel at risk of exposure to selected infectious diseases. ***FY 2022 Plans:*** Will fund civilian salaries and associated expenses (supplies, equipment, travel, etc.) at USAMRDC. Funding also provided regulatory, clinical monitoring and data support for the Special Immunization Program as necessary. This program will provide non-licensed vaccines under FDA oversight to personnel at risk of exposure to selected infectious diseases. ***FY 2021 to FY 2022 Increase/Decrease Statement:*** Funding change reflects planned lifecycle of this effort.	-	0.662	0.782
Accomplishments/Planned Programs Subtotals	-	26.711	26.521

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A