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**Exhibit R-2, RDT&E Budget Item Justification: PB 2022 Army** **Date:** May 2021

<b>Appropriation/Budget Activity</b> 2040: <i>Research, Development, Test &amp; Evaluation, Army / BA 2: Applied Research</i>	<b>R-1 Program Element (Number/Name)</b> PE 0602115A / <i>Biomedical Technology</i>
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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	-	-	11.403	11.925	-	11.925	-	-	-	-	-	-
EB2: <i>HIV Biomedical Technology</i>	-	-	11.403	11.925	-	11.925	-	-	-	-	-	-

**Note**

This Program Element (PE) is a New Start for Fiscal Year 2021 (FY21).

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

This PE funds the Military Human Immunodeficiency Virus (HIV) Research Program and the Combatting Antimicrobial Resistant Bacteria (CARB) projects. The goal of the Military HIV Research Program is to refine identification methods for determining genetic diversity of the virus, to conduct preclinical work in laboratory animals including non-human primates to identify candidates for global HIV-1 vaccine, and to evaluate and prepare overseas sites for clinical trials with these vaccine candidates. For the CARB program, funding provides for the development of strategies to prevent, mitigate, and treat antibiotic resistant bacteria in wounds through the CARB - Walter Reed Army Institute of Research (WRAIR) Discovery and Wound Program.

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

<b>B. Program Change Summary (\$ in Millions)</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022 Base</b>	<b>FY 2022 OCO</b>	<b>FY 2022 Total</b>
Previous President's Budget	0.000	11.835	12.072	-	12.072
Current President's Budget	0.000	11.403	11.925	-	11.925
Total Adjustments	0.000	-0.432	-0.147	-	-0.147
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-	-0.432			
• Adjustments to Budget Years	-	-	-0.147	-	-0.147

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**Exhibit R-2A, RDT&E Project Justification:** PB 2022 Army **Date:** May 2021

Appropriation/Budget Activity 2040 / 2					R-1 Program Element (Number/Name) PE 0602115A / <i>Biomedical Technology</i>				Project (Number/Name) EB2 / <i>HIV Biomedical Technology</i>			
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
<i>EB2: HIV Biomedical Technology</i>	-	-	11.403	11.925	-	11.925	-	-	-	-	-	-

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

The Military Human Immunodeficiency Virus (HIV) Research Program conducts research on HIV, which causes acquired immunodeficiency syndrome (AIDS). Work in this area includes refining improved identification methods to determine genetic diversity of the virus and evaluating and preparing overseas sites for clinical trials with global vaccine candidates. Additional activities include refining candidate vaccines for preventing HIV and undertaking preclinical studies (studies required before testing in humans) to assess vaccine for potential to protect and/or manage the disease in infected individuals. This project is jointly managed through an Interagency Agreement between U.S. Army Medical Research and Development Command (USAMRDC) and the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health.

The Combatting Antimicrobial Resistant Bacteria (CARB) research program was established in response to Presidential direction in late 2013 to create a National Strategy to address the critical issue of antimicrobial resistance. This effort's focus is on the development of new/novel antibiotics, especially those targeting the most resistant and worrisome Gram negative bacterial pathogens, using existing expertise at the Walter Reed Army Institute of Research (WRAIR), and leveraging other WRAIR capabilities to evaluate viable candidate targets for advanced discovery. This project supports (both directly and indirectly) Global Health Security Agenda priorities to respond rapidly and effectively to biological threats of international concern.

The cited work is also consistent with the Assistant Secretary of Defense, Research and Engineering Science and Technology focus areas, and supports the principal area of Military Relevant Infectious Diseases to include HIV.

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

	FY 2020	FY 2021	FY 2022
<b>Title:</b> HIV Biomedical Technology	-	9.631	9.956
<b>Description:</b> The Military HIV Research Program conducts research on HIV, which causes AIDS. Work in this area includes refining improved identification methods to determine genetic diversity of the virus and evaluating and preparing overseas sites for future vaccine trials. Additional activities include refining candidate vaccines for preventing HIV and undertaking preclinical studies (studies required before testing in humans) to assess vaccine for potential to protect and/or manage the disease in infected individuals.			
<b>FY 2021 Plans:</b> The Military HIV Research Program produce and characterize new vaccine candidates for use in pre-clinical and clinical testing. Vaccine candidates are evaluated to assess their ability to invoke an immune response in non-human primates by using novel delivery systems containing a diverse mixture of antigens (substance that induces an immune response) for HIV subtypes A, B, C, D and E. The program develops and optimizes methods of large scale production of new vaccine candidates for testing in Africa and Asia to assess candidate vaccines against diverse HIV subtypes. Efforts continue to identify and develop new clinical trial			

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<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>		<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
<p>sites in Europe, Southeast Africa, Asia and the US in order to allow scientists the opportunity to test future vaccine candidates against predominant HIV subtypes circulating around the world.</p> <p><b>FY 2022 Plans:</b> In FY22 Military HIV Research Program will continue to characterize next generation HIV vaccines and evaluate their capability to induce protective immune responses. The Military HIV Research Program will elucidate mechanisms by which different Army-owned adjuvants contribute to vaccine protection in monkeys. The program will leverage animal models of HIV remission to test novel treatments, including immune therapies (therapeutic vaccines and monoclonal antibodies). The program will continue to assess the HIV threat due to evolving virus genes around the world and continue to track rates of new HIV infections at likely future clinical trial sites.</p> <p><b>FY 2021 to FY 2022 Increase/Decrease Statement:</b> Funding change reflects planned lifecycle of this effort.</p>				
<p><b>Title:</b> Combatting Antimicrobial Resistant Bacteria</p> <p><b>Description:</b> The Combating Antimicrobial Resistant Bacteria (CARB) research program focus is to establish in-house capabilities for an antibacterial drug discovery program directed toward military relevant drug-resistant bacteria that a) encompasses assessment of external products/candidates/leads that may meet DoD requirements, b) opens active intramural based discovery efforts of new potential products/candidates/leads for development, and c) fosters partnerships with external collaborators to develop/co-develop new potential antibacterial treatment therapeutics.</p> <p><b>FY 2021 Plans:</b> The CARB program continues its research efforts to evaluate viable small molecule candidate antibacterial agents for planned development for the Department of Defense (DoD) and Public Health benefit. In addition, the program continues its market analysis of established, non-DoD antibiotic programs to identify other promising compounds that could potentially treat military relevant resistant bacteria, establishing partnership and intellectual property rights agreements where necessary. These promising compounds are screened against military relevant strains and biofilms (microorganisms in which cells stick to each other on a surface) in order to select compounds for continued development. Specifically designed novel drugs are synthesized to support lead optimization efforts, exploiting established in vivo (living organism) model standards to treat military relevant resistant bacteria.</p> <p><b>FY 2022 Plans:</b> The CARB program will continue to evaluate and progress viable small molecule candidate antibacterial agents by: investigating powerful front line treatments for wound infections sustained on the battlefield for combat medics to maximally increase the golden hour in support of the MDO concept; fund research to progress established, non-DoD antibiotic programs for utility against priority pathogens identified as threats to the Warfighter and design an Integrated Product Team (IPT) in order to support product maturation toward clinical development; design clinical trials to expand indications of approved or mature investigational antibiotics</p>		-	1.772	1.969

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<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>	FY 2020	FY 2021	FY 2022
to treat wound infections and/or sepsis; internally investigate an additional prototype series to lead optimization and down-select one development candidate.			
<b><i>FY 2021 to FY 2022 Increase/Decrease Statement:</i></b> Funding change reflects planned lifecycle of this effort.			
<b>Accomplishments/Planned Programs Subtotals</b>	-	11.403	11.925

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

N/A

**Remarks**

**D. Acquisition Strategy**

N/A