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**Exhibit R-2, RDT&E Budget Item Justification: PB 2023 Army** **Date:** April 2022

<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 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
Total Program Element	-	11.403	11.925	-	-	-	0.000	0.000	0.000	0.000	0.000	23.328
EB2: <i>HIV Biomedical Technology</i>	-	11.403	11.925	-	-	-	-	-	-	-	0.000	23.328

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

This Program Element (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.

<b>B. Program Change Summary (\$ in Millions)</b>	<b>FY 2021</b>	<b>FY 2022</b>	<b>FY 2023 Base</b>	<b>FY 2023 OCO</b>	<b>FY 2023 Total</b>
Previous President's Budget	11.403	11.925	0.000	-	0.000
Current President's Budget	11.403	11.925	0.000	-	0.000
Total Adjustments	0.000	0.000	0.000	-	0.000
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-	-			

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<b>COST (\$ in Millions)</b>	<b>Prior Years</b>	<b>FY 2021</b>	<b>FY 2022</b>	<b>FY 2023 Base</b>	<b>FY 2023 OCO</b>	<b>FY 2023 Total</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>	<b>Cost To Complete</b>	<b>Total Cost</b>
<i>EB2: HIV Biomedical Technology</i>	-	11.403	11.925	-	-	-	-	-	-	-	0.000	23.328

**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 United States 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)**

	<b>FY 2021</b>	<b>FY 2022</b>	<b>FY 2023</b>
<b>Title:</b> HIV Biomedical Technology	9.631	9.593	-
<b>Description:</b> The Military HIV Research Program (MHRP) 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 2022 Plans:</b> In Fiscal Year 2022 (FY22) the 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			

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<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>		<b>FY 2021</b>	<b>FY 2022</b>	<b>FY 2023</b>
<p>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 2022 to FY 2023 Increase/Decrease Statement:</b> Funding and mission realigned as part of US Army Medical Research and Development Command transfer to the Defense Health Agency in order to meet Congressional intent as outlined in NDAA 2019 (Section 711) and NDAA 2020 (Section 737). Funding transferred to Program Element 602115DHA, Project Code 372G.</p>				
<p><b>Title:</b> Combatting Antimicrobial Resistant Bacteria</p> <p><b>Description:</b> The 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 Department of Defense (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 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 Multi-Domain Operations (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 to treat wound infections and/or sepsis; internally investigate an additional prototype series to lead optimization and down-select one development candidate.</p> <p><b>FY 2022 to FY 2023 Increase/Decrease Statement:</b> Funding and mission realigned as part of US Army Medical Research and Development Command transfer to the Defense Health Agency in order to meet Congressional intent as outlined in NDAA 2019 (Section 711) and NDAA 2020 (Section 737). Funding transferred to Program Element 602115DHA, Project Code 372G.</p>		1.772	1.897	-
<p><b>Title:</b> SBIR/STTR Tax</p> <p><b>FY 2022 Plans:</b> SBIR/STTR tax.</p> <p><b>FY 2022 to FY 2023 Increase/Decrease Statement:</b> Funding transferred in accordance with Title 15 USC ?638.</p>		-	0.435	-
<b>Accomplishments/Planned Programs Subtotals</b>		11.403	11.925	-

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

N/A

**Remarks**

**D. Acquisition Strategy**

N/A