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Exhibit R-2, RDT&E Budget Item Justification: PB 2021 Army **Date:** February 2020

Appropriation/Budget Activity 2040: <i>Research, Development, Test & Evaluation, Army / BA 2: Applied Research</i>	R-1 Program Element (Number/Name) PE 0602115A / <i>Biomedical Technology</i>
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COST (\$ in Millions)	Prior Years	FY 2019	FY 2020	FY 2021 Base	FY 2021 OCO	FY 2021 Total	FY 2022	FY 2023	FY 2024	FY 2025	Cost To Complete	Total Cost
Total Program Element	-	0.000	0.000	11.835	-	11.835	12.072	12.313	12.559	12.805	0.000	61.584
EB2: <i>HIV Biomedical Technology</i>	-	0.000	0.000	11.835	-	11.835	12.072	12.313	12.559	12.805	0.000	61.584

Note

This is a new start in FY2021.

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. Program Change Summary (\$ in Millions)

	<u>FY 2019</u>	<u>FY 2020</u>	<u>FY 2021 Base</u>	<u>FY 2021 OCO</u>	<u>FY 2021 Total</u>
Previous President's Budget	0.000	0.000	0.000	-	0.000
Current President's Budget	0.000	0.000	11.835	-	11.835
Total Adjustments	0.000	0.000	11.835	-	11.835
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-	-			
• Adjustments to Budget Years	-	-	11.835	-	11.835

Change Summary Explanation

In FY21, funding was transferred to the Army from the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDTE) Program Elements 0602115DHA Projects 246A and 447A.

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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 2019	FY 2020	FY 2021 Base	FY 2021 OCO	FY 2021 Total	FY 2022	FY 2023	FY 2024	FY 2025	Cost To Complete	Total Cost
<i>EB2: HIV Biomedical Technology</i>	-	0.000	0.000	11.835	-	11.835	12.072	12.313	12.559	12.805	0.000	61.584

Note

This is a new start in FY2021.

In Fiscal Year 2021 this is a New Start.

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)

Title: HIV Biomedical Technology	FY 2019	FY 2020	FY 2021
Description: 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.	-	-	9.847
FY 2021 Plans:			

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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>		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2019	FY 2020	FY 2021
<p>The Military HIV Research Program will produce and characterize new vaccine candidates for use in pre-clinical and clinical testing. Vaccine candidates will be 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 will develop and optimize methods of large scale production of new vaccine candidates for testing in Africa and Asia to assess candidate vaccines against diverse HIV subtypes. Efforts will continue to identify and develop new clinical trial 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>FY 2020 to FY 2021 Increase/Decrease Statement: Funding transferred from the Defense Health Program (DHP) Research, Development, Test and Evaluation (RDTE) Program Element 0602115DHA Project 447A</p>				
<p>Title: Combatting Antimicrobial Resistant Bacteria</p> <p>Description: 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 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>FY 2021 Plans: The CARB program will continue 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 will continue 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 will be 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 will be synthesized to support lead optimization efforts, exploiting established in vivo (living organism) model standards to treat military relevant resistant bacteria.</p> <p>FY 2020 to FY 2021 Increase/Decrease Statement: Funding transferred from the Defense Health Program (DHP) RDTE Program Element 0602115DHA Projects 246A</p>		-	-	1.988
Accomplishments/Planned Programs Subtotals		-	-	11.835
C. Other Program Funding Summary (\$ in Millions)				
N/A				

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

Remarks

D. Acquisition Strategy

N/A