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Exhibit R-2, RDT&E Budget Item Justification: PB 2013 Army	DATE: February 2012
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APPROPRIATION/BUDGET ACTIVITY				R-1 ITEM NOMENCLATURE							
2040: <i>Research, Development, Test & Evaluation, Army</i> BA 3: <i>Advanced Technology Development (ATD)</i>				PE 0603105A: <i>MILITARY HIV RESEARCH</i>							
COST (\$ in Millions)	FY 2011	FY 2012	FY 2013 Base	FY 2013 OCO	FY 2013 Total	FY 2014	FY 2015	FY 2016	FY 2017	Cost To Complete	Total Cost
Total Program Element	25.738	22.760	6.984	-	6.984	7.111	7.216	7.321	7.445	Continuing	Continuing
H29: <i>MED PROTECT AGNST HIV</i>	6.450	6.785	6.984	-	6.984	7.111	7.216	7.321	7.445	Continuing	Continuing
T16: <i>MILITARY HIV INITIATIVES CA</i>	19.288	15.975	-	-	-	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

This program element (PE) matures and demonstrates advanced technology of candidate human immunodeficiency virus (HIV) vaccines, prepares and conducts human clinical studies to assess safety and efficacy of candidate HIV vaccines, conducts research to control HIV infection in military environments, protects the military blood supply from HIV, and protects military personnel from risks associated with the HIV infection. All HIV technology development activities are conducted in compliance with U.S. Food and Drug Administration (FDA) regulations. FDA requires thorough testing in animal models (preclinical testing) to ensure safety and efficacy prior to approving controlled clinical evaluation of drugs, vaccines, and medical devices in humans. Normally, clinical trials are conducted in three phases to prove safety and effectiveness of the drug, vaccine, and device for the targeted disease or condition. An increasing number of test subjects are used in each subsequent phase. All results are submitted to FDA for evaluation to ultimately obtain approval (licensure) for routine medical use. This program is jointly managed through an Interagency Agreement by the U.S. Army Medical Research and Materiel Command (MRMC), the National Institutes of Health, and the National Institute of Allergy and Infectious Diseases (NIAID).

This project contains no duplication with any effort within the Military Departments or other government organizations.

Work is fully coordinated with work funded in program element PE 0602787A, project 873 (HIV Exploratory Research).

The cited work is consistent with the Assistant Secretary of Defense, Research and Engineering Science and Technology focus areas and the Army Modernization Strategy.

Work in this PE is performed by the Walter Reed Army Institute of Research (WRAIR), Silver Spring, MD, and its overseas laboratories; and the Naval Medical Research Center (NMRC), Silver Spring, MD, and its overseas laboratories. The Henry M. Jackson Foundation, located in Rockville, MD, provides support for FDA testing and other research under cooperative agreement.

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BA 3: Advanced Technology Development (ATD)					
B. Program Change Summary (\$ in Millions)	FY 2011	FY 2012	FY 2013 Base	FY 2013 OCO	FY 2013 Total
Previous President's Budget	6.688	6.796	6.909	-	6.909
Current President's Budget	25.738	22.760	6.984	-	6.984
Total Adjustments	19.050	15.964	0.075	-	0.075
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	19.844	16.000			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-0.794	-			
• Adjustments to Budget Years	-	-	0.075	-	0.075
• Other Adjustments 1	-	-0.036	-	-	-

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APPROPRIATION/BUDGET ACTIVITY 2040: Research, Development, Test & Evaluation, Army BA 3: Advanced Technology Development (ATD)				R-1 ITEM NOMENCLATURE PE 0603105A: MILITARY HIV RESEARCH				PROJECT H29: MED PROTECT AGNST HIV			
COST (\$ in Millions)	FY 2011	FY 2012	FY 2013 Base	FY 2013 OCO	FY 2013 Total	FY 2014	FY 2015	FY 2016	FY 2017	Cost To Complete	Total Cost
H29: MED PROTECT AGNST HIV	6.450	6.785	6.984	-	6.984	7.111	7.216	7.321	7.445	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project funds research to develop candidate human immunodeficiency virus (HIV) vaccines, assess their safety and effectiveness in evaluation with human subjects, and protect the military personnel from risks associated with HIV infection. In addition, it is designed to find ways to protect the blood supply from contamination with the virus. All HIV technology development is conducted in compliance with U.S. Food and Drug Administration (FDA) regulations. Evaluations in human subjects are conducted to demonstrate safety and effectiveness of candidate vaccines, as required by FDA regulation. Studies are conducted stepwise: first, to prove safety; second, to demonstrate the desired effectiveness of the drug, vaccine, or device for the targeted disease or condition in a small study; and third, to demonstrate effectiveness in large, diverse human population trials. All results are submitted to the FDA for evaluation to ultimately obtain approval (licensure) for medical use. This project supports studies for effectiveness testing on small study groups after which they transition to the next phase of development for completion of effectiveness testing in larger populations.

This program is jointly managed through an Interagency Agreement by the U.S. Army Medical Research and Materiel Command (MRMC) and the National Institute of Allergy and Infectious Diseases (NIAID). This project contains no duplication with any effort within the Military Departments or other government organizations.

Work is fully coordinated with work funded in program element PE 0602787A, project 873 (HIV Exploratory Research) are further matured under PE 0603807A, project 811.

The cited work is consistent with the Assistant Secretary of Defense, Research and Engineering Science and Technology focus areas and the Army Modernization Strategy.

Work in this PE is performed by the Walter Reed Army Institute of Research (WRAIR), Silver Spring, MD, and its overseas laboratories. Significant work is conducted under a cooperative agreement with the Henry M. Jackson Foundation, Rockville, MD.

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

	FY 2011	FY 2012	FY 2013
Title: HIV Program	6.450	6.785	6.984
Description: This project funds research to develop candidate HIV vaccines, assess their safety and effectiveness in evaluations with human subjects, and protect military personnel from risks associated with HIV infection.			
FY 2011 Accomplishments:			

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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2011	FY 2012
Expanded evaluations in human volunteers in Africa and Asia to assess the safety and effectiveness of a vaccine combination designed for more than one HIV subtype. FY 2012 Plans: Perform tests under Good Laboratory Practice FDA guidelines to assess performance and ability of HIV vaccine candidates to provoke an immune response in human trials. Prepare and conduct safety studies in human volunteers with new vaccine candidates at multiple sites worldwide. FY 2013 Plans: Will conduct initial safety studies in humans with candidate vaccines consisting of multiple subtypes in clinical trial sites in Asia and Africa; conduct studies in humans to assess performance and ability of HIV vaccine candidates to provoke an immune response that can protect against HIV.			
Accomplishments/Planned Programs Subtotals		6.450	6.785
C. Other Program Funding Summary (\$ in Millions) N/A			
D. Acquisition Strategy N/A			
E. Performance Metrics Performance metrics used in the preparation of this justification material may be found in the FY 2010 Army Performance Budget Justification Book, dated May 2010.			

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COST (\$ in Millions)	FY 2011	FY 2012	FY 2013 Base	FY 2013 OCO	FY 2013 Total	FY 2014	FY 2015	FY 2016	FY 2017	Cost To Complete	Total Cost
T16: <i>MILITARY HIV INITIATIVES CA</i>	19.288	15.975	-	-	-	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification
Congressional Interest Item projects for HIV Research.

<u>B. Accomplishments/Planned Programs (\$ in Millions)</u>	FY 2011	FY 2012	FY 2013
<i>Title:</i> HIV Research <i>Description:</i> This is a Congressional Interest Item. <i>FY 2011 Accomplishments:</i> Program Increase <i>FY 2012 Plans:</i> Program Increase	19.288	15.975	-
Accomplishments/Planned Programs Subtotals	19.288	15.975	-

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

D. Acquisition Strategy
N/A

E. Performance Metrics
Performance metrics used in the preparation of this justification material may be found in the FY 2010 Army Performance Budget Justification Book, dated May 2010.