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Exhibit R-2, RDT&E Budget Item Justification: PB 2014 Army	DATE: April 2013
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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)	All Prior Years	FY 2012	FY 2013[#]	FY 2014 Base	FY 2014 OCO ^{##}	FY 2014 Total	FY 2015	FY 2016	FY 2017	FY 2018	Cost To Complete	Total Cost
Total Program Element	-	22.552	6.984	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
H29: <i>Med Protect Agnst Hiv</i>	-	6.577	6.984	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
T16: <i>MILITARY HIV INITIATIVES CA</i>	-	15.975	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

[#] FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

^{##} The FY 2014 OCO Request will be submitted at a later date

Note

FY14 realigned to the Defense Health Program.

A. Mission Description and Budget Item Justification

This PE matures and demonstrates advanced technology of candidate human immunodeficiency virus (HIV) vaccines, prepares and conducts human clinical studies to assess safety and effectiveness 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 FDA regulations. FDA requires thorough testing in animal models (preclinical testing) to ensure safety and effectiveness 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 (USAMRMC), 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 WRAIR, Silver Spring, MD, and its overseas laboratories, and NMRC, Silver Spring, MD, and its overseas laboratories. The Henry M. Jackson Foundation, located in Bethesda, 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 2012	FY 2013	FY 2014 Base	FY 2014 OCO	FY 2014 Total
Previous President's Budget	22.760	6.984	7.111	-	7.111
Current President's Budget	22.552	6.984	0.000	-	0.000
Total Adjustments	-0.208	0.000	-7.111	-	-7.111
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-0.208	-			
• Adjustments to Budget Years	-	-	-7.111	-	-7.111

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Exhibit R-2A, RDT&E Project Justification: PB 2014 Army										DATE: April 2013		
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)	All Prior Years	FY 2012	FY 2013 [#]	FY 2014 Base	FY 2014 OCO ^{##}	FY 2014 Total	FY 2015	FY 2016	FY 2017	FY 2018	Cost To Complete	Total Cost
H29: Med Protect Agnst Hiv	-	6.577	6.984	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
[#] FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012												
^{##} The FY 2014 OCO Request will be submitted at a later date												
Note												
Starting in FY 14, resources for this program were realigned from RDT&E,Army to Defense Health Program												
A. Mission Description and Budget Item Justification												
This project funds research to develop candidate HIV vaccines, to assess their safety and effectiveness in human subjects, and to 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 HIV 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 USAMRMC and 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), and 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 WRAIR, Silver Spring, MD, and its overseas laboratories. Significant work is conducted under a cooperative agreement with the Henry M. Jackson Foundation, Bethesda, MD.												
B. Accomplishments/Planned Programs (\$ in Millions)									FY 2012	FY 2013	FY 2014	
Title: HIV Program									6.577	6.984	0.000	
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.												

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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2012	FY 2013
<i>FY 2012 Accomplishments:</i> Performed tests under Good Laboratory Practice FDA guidelines to assess performance and ability of HIV vaccine candidates to provoke an immune response in human trials. Prepared and conducted safety studies in human volunteers with new vaccine candidates at multiple sites worldwide. <i>FY 2013 Plans:</i> Conduct initial safety studies in humans with candidate vaccines consisting of multiple subtypes in clinical trial sites in Asia and Africa and 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		6.577	6.984
C. Other Program Funding Summary (\$ in Millions)			
N/A			
Remarks			
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)	All Prior Years	FY 2012	FY 2013[#]	FY 2014 Base	FY 2014 OCO ^{##}	FY 2014 Total	FY 2015	FY 2016	FY 2017	FY 2018	Cost To Complete	Total Cost
T16: <i>MILITARY HIV INITIATIVES CA</i>	-	15.975	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
[#] FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012 ^{##} The FY 2014 OCO Request will be submitted at a later date												
<u>A. Mission Description and Budget Item Justification</u> Congressional Interest Item projects for HIV Research.												
<u>B. Accomplishments/Planned Programs (\$ in Millions)</u>										FY 2012	FY 2013	FY 2014
<i>Title:</i> HIV Research										15.975	0.000	0.000
<i>Description:</i> This is a Congressional Interest Item.												
<i>FY 2012 Accomplishments:</i> Program Increase												
Accomplishments/Planned Programs Subtotals										15.975	0.000	0.000
<u>C. Other Program Funding Summary (\$ in Millions)</u> N/A												
<u>Remarks</u>												
<u>D. Acquisition Strategy</u> N/A												
<u>E. Performance Metrics</u> 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.												