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**Exhibit R-2, PB 2010 Army RDT&E Budget Item Justification** **DATE:** May 2009

<b>APPROPRIATION/BUDGET ACTIVITY</b>					<b>R-1 ITEM NOMENCLATURE</b>					
2040 - Research, Development, Test & Evaluation, Army/BA 3 - Advanced Technology Development (ATD)					PE 0603105A MILITARY HIV RESEARCH					
<b>COST (\$ in Millions)</b>	<b>FY 2008 Actual</b>	<b>FY 2009 Estimate</b>	<b>FY 2010 Estimate</b>	<b>FY 2011 Estimate</b>	<b>FY 2012 Estimate</b>	<b>FY 2013 Estimate</b>	<b>FY 2014 Estimate</b>	<b>FY 2015 Estimate</b>	<b>Cost To Complete</b>	<b>Total Cost</b>
Total Program Element	14.490	15.064	6.657						Continuing	Continuing
H29: MED PROTECT AGNST HIV	6.761	7.091	6.657						Continuing	Continuing
T16: MILITARY HIV INITIATIVES CA	7.729	7.973	.000						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, prepare and conduct human clinical studies to assess safety and efficacy of candidate HIV vaccines, conduct research to control HIV infection in military environments, protect the military blood supply from HIV, and protect military personnel from risks associated with the HIV infection. All HIV technology development activities are conducted in compliance with US 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 testing 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 test 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 US 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 related to and fully coordinated with work funded in program element PE 0602787A, project 873 (HIV Exploratory Research).

The cited work is consistent with the Director, Defense Research and Engineering Strategic Plan, the Army Modernization Strategy, and the Army Science and Technology Master Plan.

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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<b>APPROPRIATION/BUDGET ACTIVITY</b> 2040 - Research, Development, Test & Evaluation, Army/BA 3 - Advanced Technology Development (ATD)	<b>R-1 ITEM NOMENCLATURE</b> PE 0603105A MILITARY HIV RESEARCH
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**B. Program Change Summary (\$ in Millions)**

	<u>FY 2008</u>	<u>FY 2009</u>	<u>FY 2010</u>	<u>FY 2011</u>
Previous President's Budget	14.903	7.116	6.766	
Current BES/President's Budget	14.490	15.064	6.657	
Total Adjustments	-.413	7.948	-.109	
Congressional Program Reductions	.000	-.052		
Congressional Rescissions	.000	.000		
Total Congressional Increases	.000	8.000		
Total Reprogrammings	.005	.000		
SBIR/STTR Transfer	-.418	.000		

**Change Summary Explanation**

FY09 increase is due to congressional adds.

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<b>Exhibit R-2a, PB 2010 Army RDT&amp;E Project Justification</b>								<b>DATE:</b> May 2009		
<b>APPROPRIATION/BUDGET ACTIVITY</b> 2040 - Research, Development, Test & Evaluation, Army/BA 3 - Advanced Technology Development (ATD)				<b>R-1 ITEM NOMENCLATURE</b> PE 0603105A MILITARY HIV RESEARCH					<b>PROJECT NUMBER</b> H29	
<b>COST (\$ in Millions)</b>	<b>FY 2008 Actual</b>	<b>FY 2009 Estimate</b>	<b>FY 2010 Estimate</b>	<b>FY 2011 Estimate</b>	<b>FY 2012 Estimate</b>	<b>FY 2013 Estimate</b>	<b>FY 2014 Estimate</b>	<b>FY 2015 Estimate</b>	<b>Cost To Complete</b>	<b>Total Cost</b>
H29: MED PROTECT AGNST HIV	6.761	7.091	6.657						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 testing 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 US Food and Drug Administration (FDA) regulations. Tests in human subjects are conducted to demonstrate safety and effectiveness, 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 test 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 US 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 related to and 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 Director, Defense Research and Engineering Strategic Plan, the Army Modernization Strategy, and the Army Science and Technology Master Plan.

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. Most work is conducted under a cooperative agreement with the Henry M. Jackson Foundation, Rockville, MD.

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

	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
HIV Program: In FY08, continued with HIV vaccine development and clinical testing of new candidate vaccines, including maintaining the facilities required to assess clinical samples and show vaccine safety and effectiveness; continued long-term clinical follow-up of vaccinated volunteers; and continued to develop and maintain new clinical trial sites in Africa and Asia to maintain a sufficient base of potential volunteers for testing of vaccines under development by the U.S. Government. In FY09, assess ongoing vaccine trials to down-select various candidates and further develop vaccines. Test human volunteers in the US and Africa to assess the safety and physiological response of vaccines prepared with additional HIV subtypes (strains of the HIV virus). Will continue large scale human studies testing in	6.761	6.891	6.657	

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<b>B. Accomplishments/Planned Program (\$ in Millions)</b>			<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
Thailand to assess the effectiveness of the vaccine candidate that has previously shown good safety profiles. In FY10, will test in human volunteers in Africa to assess the safety and physiological response of vaccines prepared with additional HIV subtypes. Will continue large scale testing in humans in Thailand.						
Small Business Innovative Research/Small Business Technology Transfer Programs			.000	.200	.000	
Total			6.761	7.091	6.657	
<b>C. Other Program Funding Summary (\$ in Millions)</b> N/A						
<b>D. Acquisition Strategy</b> N/A						
<b>E. Performance Metrics</b> 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 2008 Actual	FY 2009 Estimate	FY 2010 Estimate	FY 2011 Estimate	FY 2012 Estimate	FY 2013 Estimate	FY 2014 Estimate	FY 2015 Estimate	Cost To Complete	Total Cost
T16: MILITARY HIV INITIATIVES CA	7.729	7.973	.000						Continuing	Continuing

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

This is a Congressional Interest Item

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

	FY 2008	FY 2009	FY 2010	FY 2011
HIV Research	7.729	7.750	.000	
SBIR/STTR	.000	.223	.000	
Total	7.729	7.973	.000	

**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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