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Exhibit R-2, PB 2011 Army RDT&E Budget Item Justification									DATE: February 2010		
APPROPRIATION/BUDGET ACTIVITY 2040: Research, Development, Test & Evaluation, Army BA 3: Advanced Technology Development (ATD)				R-1 ITEM NOMENCLATURE PE 0603105A: MILITARY HIV RESEARCH							
COST (\$ in Millions)	FY 2009 Actual	FY 2010 Estimate	Base FY 2011 Estimate	OCO FY 2011 Estimate	Total FY 2011 Estimate	FY 2012 Estimate	FY 2013 Estimate	FY 2014 Estimate	FY 2015 Estimate	Cost To Complete	Total Cost
Total Program Element	14.867	29.502	6.688	0.000	6.688	6.796	6.909	7.031	7.139	0	85.620
H29: MED PROTECT AGNST HIV	6.892	6.622	6.688	0.000	6.688	6.796	6.909	7.031	7.139	Continuing	Continuing
T16: MILITARY HIV INITIATIVES CA	7.975	22.880	0.000	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
A. Mission Description and Budget Item Justification											
<p>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.</p>											

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B. Program Change Summary (\$ in Millions)					
	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
Previous President's Budget	15.064	6.657	6.723	0.000	6.723
Current President's Budget	14.867	29.502	6.688	0.000	6.688
Total Adjustments	-0.197	22.845	-0.035	0.000	-0.035
• Congressional General Reductions		-0.155			
• Congressional Directed Reductions					
• Congressional Rescissions		0.000			
• Congressional Adds		23.000			
• Congressional Directed Transfers					
• Reprogrammings	0.226	0.000			
• SBIR/STTR Transfer	-0.423	0.000			
• Adjustments to Budget Years	0.000	0.000	-0.035	0.000	-0.035
Change Summary Explanation					
FY10 Congressionally directed increases.					

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COST (\$ in Millions)	FY 2009 Actual	FY 2010 Estimate	Base FY 2011 Estimate	OCO FY 2011 Estimate	Total FY 2011 Estimate	FY 2012 Estimate	FY 2013 Estimate	FY 2014 Estimate	FY 2015 Estimate	Cost To Complete	Total Cost
H29: <i>MED PROTECT AGNST HIV</i>	6.892	6.622	6.688	0.000	6.688	6.796	6.909	7.031	7.139	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. Significant work is conducted under a cooperative agreement with the Henry M. Jackson Foundation, Rockville, MD.

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

	FY 2009	FY 2010	Base FY 2011	OCO FY 2011	Total FY 2011
Program #1 HIV Program: In FY09, assessed ongoing vaccine trials to down-select various candidates and further develop vaccines. Tested 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). Continued large scale human studies testing in Thailand to assess the effectiveness of the vaccine candidate that has previously shown good safety profiles. In FY10, test in human volunteers in Africa to assess the safety and physiological response of vaccines prepared with additional HIV subtypes. Continue large scale testing in humans in Thailand. In FY11, if	6.892	6.436	6.688	0.000	6.688

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B. Accomplishments/Planned Program (\$ in Millions)					
	FY 2009	FY 2010	Base FY 2011	OCO FY 2011	Total FY 2011
warranted, will expand testing 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 2009 Accomplishments: FY 2009 FY 2010 Plans: FY 2010 Base FY 2011 Plans: FY 2011 Base OCO FY 2011 Plans: FY 2011 OCO					
Program #2 Small Business Innovative Research/Small Business Technology Transfer Programs FY 2009 Accomplishments: FY 2009 FY 2010 Plans: FY 2010 Base FY 2011 Plans: FY 2011 Base OCO FY 2011 Plans: FY 2011 OCO	0.000	0.186	0.000	0.000	0.000

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<u>B. Accomplishments/Planned Program (\$ in Millions)</u>								
				FY 2009	FY 2010	Base FY 2011	OCO FY 2011	Total FY 2011
Accomplishments/Planned Programs Subtotals				6.892	6.622	6.688	0.000	6.688
<u>C. Other Program Funding Summary (\$ in Millions)</u> N/A								
<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.								

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COST (\$ in Millions)	FY 2009 Actual	FY 2010 Estimate	Base FY 2011 Estimate	OCO FY 2011 Estimate	Total FY 2011 Estimate	FY 2012 Estimate	FY 2013 Estimate	FY 2014 Estimate	FY 2015 Estimate	Cost To Complete	Total Cost
T16: <i>MILITARY HIV INITIATIVES CA</i>	7.975	22.880	0.000	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
<u>A. Mission Description and Budget Item Justification</u> Congressional Interest Item projects for HIV Research.											
<u>B. Accomplishments/Planned Program (\$ in Millions)</u>											
							FY 2009	FY 2010	Base FY 2011	OCO FY 2011	Total FY 2011
Program #1 Test, Treatment and Preventive Vaccines. This Congressional Interest Item conducts research into human immunodeficiency virus. <i>FY 2009 Accomplishments:</i> FY 2009 <i>FY 2010 Plans:</i> FY 2010 <i>Base FY 2011 Plans:</i> FY 2011 Base <i>OCO FY 2011 Plans:</i> FY 2011 OCO							7.975	19.896	0.000	0.000	0.000
Program #2 HIV Prevention and Reducing Risk to US Military Personnel. This is a Congressional Interest Item							0.000	2.984	0.000	0.000	0.000

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<u>B. Accomplishments/Planned Program (\$ in Millions)</u>						
		FY 2009	FY 2010	Base FY 2011	OCO FY 2011	Total FY 2011
<i>FY 2009 Accomplishments:</i> FY 2009 <i>FY 2010 Plans:</i> FY 2010 <i>Base FY 2011 Plans:</i> FY 2011 Base <i>OCO FY 2011 Plans:</i> FY 2011 OCO						
Accomplishments/Planned Programs Subtotals		7.975	22.880	0.000	0.000	0.000
<u>C. Other Program Funding Summary (\$ in Millions)</u> N/A						
<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.						

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