

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R2 Exhibit)

February 2008

BUDGET ACTIVITY		PE NUMBER AND TITLE					
3 - Advanced technology development		0603105A - MILITARY HIV RESEARCH					
COST (In Thousands)	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	FY 2010 Estimate	FY 2011 Estimate	FY 2012 Estimate	FY 2013 Estimate
Total Program Element (PE) Cost	12559	14903	7116	6766	6895	7049	7207
H29	MED PROTECT AGNST HIV	6749	6954	7116	6766	6895	7049
T16	MILITARY HIV INITIATIVES CA	5810	7949				

A. Mission Description and Budget Item Justification: This project matures and demonstrates advanced technology of candidate human immunodeficiency virus (HIV) vaccines, prepares and conducts human clinical studies to assess safety and efficacy (effectiveness) of candidate HIV vaccines, conducts research to control HIV infection in military environments, protect the military blood supply, and protect military personnel from risks associated with HIV infection. All HIV technology development activities are conducted in compliance with U.S. Food and Drug Administration (FDA) regulations and conducted under an Investigational New Drug application with FDA. 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 (Phase 1, 2, and 3) to prove safety and effectiveness of the drug/vaccine/device for the targeted disease/condition. An increasing number of people 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 U.S. Army Medical Research and Materiel Command and the National Institute of Allergy and Infectious Diseases. 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. The cited work is consistent with the Department of Defense Research and Engineering Strategic Plan, the Army Science and Technology Master Plan, the Army Modernization Strategy, and the Army Posture Statement. Work in this PE is performed by the Walter Reed Army Institute of Research, Rockville, Maryland, and its overseas laboratories; and the Naval Medical Research Center, Silver Spring, Maryland, and its overseas laboratories. Most work is conducted under a cooperative agreement with the Henry M. Jackson Foundation, Rockville, Maryland.

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<u>B. Program Change Summary</u>	FY 2007	FY 2008	FY 2009
Previous President's Budget (FY 2008/2009)	12897	6998	7162
Current BES/President's Budget (FY 2009)	12559	14903	7116
Total Adjustments	-338	7905	-46
Congressional Program Reductions		-95	
Congressional Recissions			
Congressional Increases		8000	
Reprogrammings	25		
SBIR/STTR Transfer	-363		
Adjustments to Budget Years			-46
One FY08 congressional adds totaling \$8000 were added to this PE.			
(\$8000) HIV Research			

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February 2008

BUDGET ACTIVITY 3 - Advanced technology development		PE NUMBER AND TITLE 0603105A - MILITARY HIV RESEARCH					PROJECT H29	
COST (In Thousands)	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	FY 2010 Estimate	FY 2011 Estimate	FY 2012 Estimate	FY 2013 Estimate	
H29 MED PROTECT AGNST HIV	6749	6954	7116	6766	6895	7049	7207	

A. Mission Description and Budget Item Justification: This project matures and demonstrates advanced technology of candidate human immunodeficiency virus (HIV) vaccines, prepares and conducts human clinical studies to assess safety and efficacy (effectiveness) of candidate HIV vaccines, matures and assesses methods to control HIV infection in military environments, protect the military blood supply, and protect military personnel from risks associated with HIV infection. All HIV technology development activities are conducted in compliance with U.S. Food and Drug Administration (FDA) regulations and conducted under an Investigational New Drug application with FDA. 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 (Phase 1, 2, and 3) to prove safety and effectiveness of the drug/vaccine/device for the targeted disease/condition. An increasing number of people 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 U.S. Army Medical Research and Materiel Command and the National Institute of Allergy and Infectious Diseases. 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. The cited work is consistent with the Department of Defense Research and Engineering Strategic Plan, the Army Science and Technology Master Plan, the Army Modernization Strategy, and the Army Posture Statement. Work in this PE is performed by the Walter Reed Army Institute of Research, Rockville, Maryland, and its overseas laboratories; and the Naval Medical Research Center, Silver Spring, Maryland, and its overseas laboratories. Most work is conducted under a cooperative agreement with the Henry M. Jackson Foundation, Rockville, Maryland.

<u>Accomplishments/Planned Program:</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>
HIV Program: Complete preclinical testing (studies required by FDA prior to testing in humans) and conduct manufacturing and clinical studies of HIV vaccine candidates. In FY07, conducted vaccine test site development and conducted clinical studies, including transition to the next phase of clinical testing of two vaccines involving up to 300 human subjects and long-term (up to 3 years) follow-up of subjects from completed trials; continued activities required to support HIV vaccine development including regulatory reporting on conduct of clinical trials to the FDA; assessed clinical materials to understand responses to vaccines; and maintained clinical trial facilities in the U.S. and international field trial sites in Kenya, Uganda, and Tanzania. In FY08, continue 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; continue long-term clinical follow-up of vaccinated subjects; and continue to develop and maintain new clinical trial sites in Africa and Asia to maintain a sufficient base of potential subjects for testing of vaccines under development by the U.S. Government. In FY09, will continue to assess ongoing vaccine trials to down-select various candidates and continue activities in support of vaccines under development.	6749	6759	7116
Small Business Innovative Research/Small Business Technology Transfer Programs		195	
Total	6749	6954	7116