

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R2 Exhibit)						February 2006	
BUDGET ACTIVITY 3 - Advanced technology development			PE NUMBER AND TITLE 0603105A - MILITARY HIV RESEARCH			PROJECT H29	
COST (In Thousands)	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	FY 2010 Estimate	FY 2011 Estimate
H29 MED PROTECT AGNST HIV	13545	13644	7042	7052	7175	6814	6944
<p>A. Mission Description and Budget Item Justification: This project supports the medical technology area of the Future Force by conducting advanced technology development of candidate vaccines to include safety and efficacy in model systems and to prepare and conduct clinical studies. It funds human immunodeficiency virus (HIV) research to control the infection in military environments, protect the military blood supply, and protect military personnel from risks associated with infection. HIV research is focused on the following areas: diagnosis, natural history, epidemiology, and vaccine development. All HIV research is conducted in compliance with U.S. Food and Drug Administration (FDA) regulations and conducted under an Investigational New Drug (IND) application with the FDA. The FDA requires thorough testing in animals (referred to as preclinical testing) to assure safety and efficacy prior to approving controlled clinical testing of experimental (previously unproven in humans) 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 the FDA for evaluation to obtain approval 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 PE 0602787. The cited work is consistent with Strategic Planning Guidance, the Army Science and Technology Master Plan (ASTMP), the Army Modernization Plan, and the Defense Technology Area Plan (DTAP). Work in this program element 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 (HMJF), Rockville, MD.</p>							
Accomplishments/Planned Program				FY 2005	FY 2006	FY 2007	
Medical Protection Against HIV: In FY05, continued to study a variety of vaccine technologies to assess their ability to impact HIV infection and disease: completed preclinical testing of a DNA vaccine that includes different type of gene strains coupled with a vaccine made by using a nonpathogenic, infective adenovirus into which HIV genes have been inserted; continued clinical efficacy trials of previously developed DNA Plasmid HIV vaccine(s) and began safety trial of a poxvirus based vaccine in East Africa; improved tests needed to assess HIV vaccine-induced immune responses; and continued to conduct a multicenter clinical study to investigate HIV drug resistance. In FY06, evaluate the immunogenicity/efficacy of best vaccine candidates in clinical safety and immunogenicity trials as appropriate, and other activities required for vaccine development and testing such as assay improvement, preclinical testing, field site development, preparation and submission of FDA required data packages. In FY07, will continue the next phases of clinical testing of the pox, adenoviral, and anthrax lethal factor based vaccines; and will continue development activities required to support vaccine development, clinical trial site development and assay improvement.				6354	6644	7042	
HIV Research: This 1-year Congressional add funded additional research on, and preclinical testing, of a DNA-based vaccine candidate co-developed with the National Institute of Allergy and Infectious Diseases, as well as the preparation for clinical trials of this vaccine at several African field test sites requiring the establishment of clinics and laboratory facilities and training of personnel to conduct these trials.				7191	7000	0	
Total				13545	13644	7042	

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<u>B. Program Change Summary</u>	FY 2005	FY 2006	FY 2007	
Previous President's Budget (FY 2006)	13552	6842	7131	
Current BES/President's Budget (FY 2007)	13545	13644	7042	
Total Adjustments	-7	6802	-89	
Congressional Program Reductions		-60		
Congressional Rescissions		-138		
Congressional Increases		7000		
Reprogrammings	-7			
SBIR/STTR Transfer				
Adjustments to Budget Years			-89	
One FY06 Congressional add totaling \$7000 was added to this PE.				
FY06 Congressional add with no R-2A (appropriated amount is shown): (\$7000) Test, Treatment and Preventive Vaccines				