

<b>ARMY RDT&amp;E BUDGET ITEM JUSTIFICATION (R2 Exhibit)</b>						<b>February 2005</b>				
BUDGET ACTIVITY <b>3 - Advanced technology development</b>			PE NUMBER AND TITLE <b>0603105A - MILITARY HIV RESEARCH</b>				PROJECT <b>H29</b>			
COST (In Thousands)			FY 2004 Actual	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			13708	13552	6842	7131	7145	7143	7285	7430
<p><b><u>A. Mission Description and Budget Item Justification:</u></b> This project supports the medical technology area of the Future Force by conducting concept exploration 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. Preclinical trials and Phase 1 and 2 clinical trials are performed as required for vaccine licensure with the U.S. Food and Drug Administration (FDA). 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, Silver Spring, MD and its overseas laboratories; and the Naval Medical Research Center, Silver Spring, MD and its overseas laboratories. Most work is conducted under a cooperative agreement with the Henry M. Jackson Foundation, Rockville, MD.</p>										

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<u>Accomplishments/Planned Program</u>	FY 2004	FY 2005	FY 2006	FY 2007
<p>In FY04, identified appropriate populations for clinical trials for development of selected candidate vaccines in East Africa; established diagnostic capabilities needed to differentiate vaccine-induced immune response from HIV infection in clinical trials; conducted preclinical studies of candidate HIV vaccines in animal models to determine safety and induction of immune response before studies are begun in humans; conducted a multicenter clinical study to investigate HIV drug resistance for clinical trials.</p> <p>In FY05, continue clinical trials of DNA/Adenoviral HIV vaccine(s) in East Africa and other new and improved HIV vaccine candidates; continue to identify appropriate populations for system development and demonstration (SDD) of selected candidate vaccines in East Africa; establish further diagnostic capabilities needed to differentiate vaccine-induced immune response from HIV infection in clinical trials, improve tests needed to assess HIV vaccine-induced immune responses; continue to conduct preclinical studies of candidate HIV vaccines in animal models to determine safety and induction of immune response before studies are begun in humans; continue to conduct a multicenter clinical study to investigate HIV drug resistance; conduct Phase 2 clinical testing of HIV vaccine candidates for transition to SDD if appropriate.</p> <p>In FY06, will evaluate the immunogenicity/efficacy of best vaccine candidates in Phase 2/3 clinical trials as appropriate and other activities required for vaccine development and testing such as assay improvement, preclinical testing, Investigational New Drug application writing and submission, and clinical data analysis.</p> <p>In FY07, will continue the clinical testing and support activities as dictated by the testing results and the FDA.</p>	6502	6361	6842	7131
<p>This one year Congressional add funds additional development and preclinical testing of a DNA based vaccine candidate co-developed with the National Institute of Allergy and Infectious Diseases, as well as 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.</p>	7206	7191	0	0
<b>Totals</b>	<b>13708</b>	<b>13552</b>	<b>6842</b>	<b>7131</b>

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**H29****B. Program Change Summary**

	FY 2005	FY 2006	FY 2007
Previous President's Budget (FY 2005)	6641	6842	6993
Current Budget (FY 2006/2007 PB)	13552	6842	7131
Total Adjustments	6911	0	138
Net of Program/Database Changes			
Congressional Program Reductions	-199		
Congressional Rescissions			
Congressional Increases	7500		
Reprogrammings			
SBIR/STTR Transfer	-390		
Adjustments to Budget Years			138

## Change Summary Explanation:

One FY05 Congressional add totaling \$7500 was added to this PE.

FY05 Congressional add with no R-2A:

(\$7193) Test, Treatment and Preventive Vaccines, Project H29. The objective of this one year Congressional add is to fund applied HIV research. No additional funding is required to complete this project.