

<b>ARMY RDT&amp;E BUDGET ITEM JUSTIFICATION (R-2 Exhibit)</b>						<b>February 2003</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 2002 Actual	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate
H29      MED PROTECT AGNST HIV			5697	0	6733	6746	6956	7111	7121	7117
<p><b><u>A. Mission Description and Budget Item Justification:</u></b> This project supports the medical technology area of the Objective Force by conducting concept exploration of candidate vaccines to include safety and efficacy in model systems to prepare and conduct clinical studies. It funds Acquired Immune Deficiency Syndrome (AIDS) research to control the infection in military environments, protect the military blood supply, and protect military personnel from risks associated with infection. AIDS research is focused on the following areas: diagnosis, natural history, epidemiology, and vaccine development. Pre-clinical trials and phase 1, 2, and 3 clinical trials are performed as required for drug and vaccine licensure with US Food and Drug Administration. The cited work is consistent with the Army Science and Technology Master Plan (ASTMP), the Army Modernization Plan and Project Reliance. The program element contains no duplication with any effort within the Military Departments. This program supports the Objective Force transition path of the Transformation Campaign Plan (TCP).</p> <p>There are no Defense Emergency Response Funds provided to this program or project.</p>										

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Accomplishments/Planned Program		FY 2002	FY 2003	FY 2004	FY 2005	
FY02, continued to prepare for HIV vaccine testing in Africa by studying the different types of HIV present. Evaluated immune responses to HIV in individuals enrolled in HIV vaccine trials. Developed a candidate HIV-1 vaccine using a modified vaccinia viral backbone and performed pre-clinical evaluations. Continued development of vaccine test and evaluation field sites in East Africa and Cameroon. Continued surveillance for new and emerging HIV subtypes within Eastern Europe, Africa and the Middle East. FY03 HIV program transferred to the National Institutes of Health (NIH). FY04, HIV program was returned to the Army. Produce clinical-grade quantities of candidate vaccines against HIV subtypes D and A. Initiate phase 1 study of a candidate HIV vaccine(s) in East Africa and other new and improved HIV vaccine candidates. Identify appropriate populations for advanced development of selected candidate vaccines in East Africa. Establish diagnostic capabilities needed to differentiate vaccine-induced immune response from HIV infection in clinical trials. Improve tests needed to assess immune responses induced by HIV vaccines. Conduct pre-clinical studies of candidate HIV vaccines in animal models to determine safety and induction of responses before studies are begun in humans. Conduct a multi-center clinical study to investigate HIV drug resistance. Begin phase 2 clinical testing for selected HIV vaccine candidates for transition to advanced development by FY06. FY05, continue multi-year efforts from prior year.		5697	0	6733	6746	
Totals		5697	0	6733	6746	

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<b><u>B. Program Change Summary</u></b>	<b>FY 2002</b>	<b>FY 2003</b>	<b>FY 2004</b>	<b>FY 2005</b>
Previous President's Budget (FY 2003)	5885	0	0	0
Current Budget (FY 2004/2005 PB)	5697	0	6733	6746
Total Adjustments	-188	0	6733	6746
Congressional program reductions				
Congressional rescissions				
Congressional increases				
Reprogrammings	-25			
SBIR/STTR Transfer	-163			
Adjustments to Budget Years			6733	6746

Change Summary Explanation: Funding – In FY 2003 program responsibility for management and oversight of HIV R&D efforts was transferred to the National Institutes of Health (NIH). In FY 2004 program was returned to the Army.