

<b>ARMY RDT&amp;E BUDGET ITEM JUSTIFICATION (R2 Exhibit)</b>					<b>February 2004</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 2003 Actual	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate
H29	MED PROTECT AGNST HIV		0	14059	6641	6842	6993	6999	6996
<p><b>A. Mission Description and Budget Item Justification:</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 and, where feasible, exploits opportunities to enhance Current Force capabilities. 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, 2, and 3 clinical trials are performed as required for vaccine licensure with U.S. Food and Drug Administration. This program is jointly managed through an Interagency Agreement by the U.S. Army Medical Research and Materiel Command (USAMRMC) and the National Institute of Allergy and Infectious Diseases. The cited work is consistent with Strategic Planning Guidance, the Army Science and Technology Master Plan, the Army Modernization Plan, and the Defense Technology Area Plan. 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. This project contains no duplication with any effort within the Military Departments.</p>									

# ARMY RDT&E BUDGET ITEM JUSTIFICATION (R2 Exhibit)

February 2004

BUDGET ACTIVITY

**3 - Advanced technology development**

PE NUMBER AND TITLE

**0603105A - MILITARY HIV RESEARCH**

PROJECT

**H29**

## Accomplishments/Planned Program

HIV - In FY03 the HIV program transferred to the National Institute of Health (NIH). Program returned to USAMRMC in FY04. In FY04, produce clinical-grade quantities of candidate vaccines against HIV subtypes D and A. Start Phase 1 study of a candidate DNA/Adenoviral 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 HIV vaccine-induced immune responses. Conduct preclinical studies of candidate HIV vaccines in animal models to determine safety and induction of immune response before studies are begun in humans. Conduct a multicenter clinical study to investigate HIV drug resistance. Begin Phase 2 clinical testing for HIV vaccine candidates for transition to advanced development by FY06. In FY05, will continue multiyear DNA/Adenoviral HIV vaccine Phase I clinical testing begun in FY04 to demonstrate safety and immunogenicity.

FY 2003

0

FY 2004

6456

FY 2005

6641

The objective of this one year Congressional add is to fund applied HIV research. No additional funding is required to complete this project

0

7193

0

Small Business Innovative Research/Small Business Technology Transfer Programs

0

410

0

Totals

0

14059

6641

## B. Program Change Summary

FY 2003

FY 2004

FY 2005

Previous President's Budget (FY 2004)

0

6733

6746

Current Budget (FY 2005 PB)

0

14059

6641

Total Adjustments

0

7326

-105

Congressional program reductions

-121

Congressional rescissions

Congressional increases

7500

Reprogrammings

-53

SBIR/STTR Transfer

Adjustments to Budget Years

-105