

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2 Exhibit)							June 2001				
BUDGET ACTIVITY 3 - ADV TECHNOLOGY DEV				PE NUMBER AND TITLE 0603105A - Military HIV Research				PROJECT H29			
COST (In Thousands)		FY 2000 Actual	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	Cost to Complete	Total Cost
H29 MED PROTECT AGNST HIV		5771	5834	5937	0	0	0	0	0	0	0
<p><u>A. Mission Description and Budget Item Justification:</u> <u>PLEASE NOTE:</u> This administration has not addressed FY2003-2007 requirements. All FY 2003-2007 budget estimates included in this book are notional only and subject to change.</p> <p>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. Preclinical 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. Major contractors are the Henry M. Jackson Foundation, Rockville MD and the Armed Forces Research Institute of Medical Science, Bangkok, Thailand. This program supports the Objective Force transition path of the Transformation Campaign Plan (TCP).</p> <p><u>FY 2000 Accomplishments</u></p> <ul style="list-style-type: none"> • 5771 - Completed a phase 2 clinical trial that demonstrated the safety (preliminary data) of a strain-specific (subtypes B and E) vaccine candidate in Thailand. Immunogenicity data is pending data scrub. - Began a phase 1/2 clinical trial of a strain-specific (subtypes B and E), canary pox-vectored HIV vaccine in Thailand. Conducted long-term follow-up of vaccine trial in human volunteers in Thailand. Study of follow-up results is underway. - Conducted phase 1 clinical trials of complex protein and novel vectored candidate vaccines. Conducted a phase 1 clinical study of Therapore-HIV vaccine in the U.S. Study of results is underway. - Conducted studies to develop/select a method for genotyping clinical HIV isolates for drug resistance for use in clinical management of military personnel with HIV infection. - Based on preliminary testing data, selected 3 candidate rapid test devices for HIV for further development and licensure for use in medical management of U.S. military personnel after exposure to blood or blood products and for emergency screening of blood donors and/or supplies. <p>Total 5771</p>											

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PROJECT

H29**FY 2001 Planned Program**

- 5660 - Conduct specialized laboratory studies of HIV virus and human host cell interactions, including virus entry into human cells, targeting of HIV vaccines to human immune cells, binding of candidate vaccines to human immune cells, and studies of HIV virus and immune system factors that are associated with immunity.
 - Conduct phase 1 and 2 clinical trials of candidate vaccines and novel vaccine delivery systems to test safety and the ability to produce an immune response.
 - Prepare a field site for large-scale field trials of candidate vaccines including an epidemiological study of the test population, preparation and education of population test cohorts, and establishing the trial site infrastructure.
 - Conduct a clinical study of the benefit of drug resistance testing on clinical management of HIV-infected patients. Continue to evaluate promising rapid tests with large volume testing. Data will support and stimulate further commercial development and licensure by commercial manufacturers.
- 174 - Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs.

Total 5834

FY 2002 Planned Program

- 5937 - Conduct specialized laboratory studies to define HIV virus and immune system factors that are associated with immunity.
 - Conduct phase 1 clinical trials of candidate vaccines and novel vaccine delivery systems (e.g., recombinant anthrax-vectored vaccine and VEE replicon particles) to test safety and the immune response.
 - Continue preparations for large-scale field trials including, epidemiological study of the test population, preparation and education of population test cohorts, and preparation of trial site infrastructure.
 - Conduct extensive testing of candidate rapid HIV testing devices to allow selection of the best devices to develop HIV testing algorithms applicable to field settings, including hospitals, troop medical clinics and blood banks.

Total 5937

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<u>B. Program Change Summary</u>	FY 2000	FY 2001	FY 2002	FY 2003
Previous President's Budget (FY2001 PB)	5931	5889	5911	0
Appropriated Value	5976	5889	0	0
Adjustments to Appropriated Value	0	0	0	0
a. Congressional General Reductions	0	0	0	0
b. SBIR / STTR	-160	0	0	0
c. Omnibus or Other Above Threshold Adjustments	-24	0	0	0
d. Below Threshold Reprogramming	0	0	0	0
e. Rescissions	-21	-55	0	0
Adjustments to Budget Years Since FY2001 PB	0	0	26	0
Current Budget Submit (FY 2002/2003 PB)	5771	5834	5937	0