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**New Trial Seeks to Find a SMARTer Way to Treat HIV**

**Washington, DC, January 10, 2002:** The Community Programs for Clinical Research on AIDS (CPCRA) announces the start of the SMART Study (Strategies for Management of Antiretroviral Therapy). The study is being carried out by 16 units in the CPCRA, 5 other sites in the United States, and sites in Australia associated with the Australian National Centre in HIV Epidemiology and Clinical Research (NCHECR). The sponsor of the study is the National Institute of Allergy and Infectious Diseases, a component of the National Institutes of Health.

According to Claire Rappoport, an AIDS activist from San Francisco and a member of the SMART protocol team, "The new anti-HIV drugs have given many people longer, healthier lives, but serious questions remain about how best to use the medications to get the maximum, long-term benefit and to minimize long-term side effects. Clinicians and patients have been making crucial treatment decisions on far too little data."

The study will enroll 6,000 people above the age of 13 over a 3-year period. Participants will be followed for 6 - 9 years to quantify the risks and benefits of two different ways of treating HIV infection. Half of the participants will be randomly assigned to the Viral Suppression or "Go group," a treatment strategy in keeping with the current HIV treatment guidelines for adults and adolescents. In this group, antiretroviral drugs will be used continuously to suppress levels of HIV in the blood to low or undetectable levels. The other half of the participants will be randomly assigned to the Drug Conservation or "Wait group." In this group, antiretroviral drugs will be used episodically only when the participants' CD4+ T-cell counts drop below 250 cells/mm<sup>3</sup>; therapy will be discontinued when the CD4+ T-cell count rises above 350 cells/mm<sup>3</sup>. "This approach of not using antiretroviral medications when CD4+ T-cell counts are higher and when the risks of complications of HIV are low could have the advantage of reducing side effects, drug resistance and cost, while saving antiretroviral medication options for a time when the risk of complications from HIV begins to increase," according to Dr. Wafaa El-Sadr,

principal investigator at Harlem Hospital and Columbia University in New York and co-chair of the study.

The SMART study also will gather information on important questions such as differences in body composition and body fat distribution, quality of life and cost effectiveness, drug resistance, and HIV transmission risk, in the two study arms.

“The initiation of the SMART study marks an important turning point in HIV research,” says James Neaton, Ph.D., principal investigator at the CPCRA Statistical Center at the University of Minnesota in Minneapolis and co-chair of the SMART study team. “Randomized evidence from large, long-term trials could substantially improve the management of HIV disease. Up until this point, we have relied heavily on the results of shorter-term, randomized trials that measured viral load and on observational studies to guide HIV management decisions. Because people with HIV are living longer and will potentially be on therapy for decades, longer-term trials comparing clinical outcomes are needed to fully understand the impact of HIV treatment decisions.”

“A trial of this scope and length will be a challenge,” says Dr. El-Sadr. “The SMART study, will address questions that are uppermost in the minds of people with HIV and the clinicians who treat them. While significant advances have been made in the treatment of HIV, after two decades we still do not know for certain that the current method of treating HIV, with continuous therapy to maximally suppress viral load, is the best way to manage HIV in the long-run.”

“The CPCRA is uniquely positioned to lead this effort,” according to Dr. Fred Gordin of the Veteran’s Affairs Medical Center in Washington, D.C. and the CPCRA Group Leader. “The CPCRA network was initiated by the NIH in 1989 to expand research opportunities to communities of color, to women, and to others affected by HIV, such as intravenous drug users. The CPCRA has research sites located in primary care settings in areas of the country hardest hit by the HIV epidemic.” Since 1989, the CPCRA has enrolled over 17,000 patients in 19 randomized and 6 observational studies and has contributed data for the development of Public Health Service guidelines for management of a range of opportunistic infections associated with HIV infection.

For more information visit the SMART Study web site at <http://www.smart-trial.org/>  
and the CPCRA web site at <http://www.cpcra.org/>.

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The SMART Study is being conducted at the following locations in the U.S. and Australia; each location may have multiple clinical sites.

### **PARTICIPATING U.S. CENTERS**

#### **CALIFORNIA**

Community Consortium of San Francisco †  
Donald Abrams, M.D., Principal Investigator

VA of Greater Los Angeles ‡  
Matthew Goetz, M.D., Principal Investigator

#### **COLORADO**

Denver CPCRA †  
David Cohn M.D., Principal Investigator

#### **CONNECTICUT**

New England Program for AIDS Clinical Trials †  
Gerald Friedland, M.D., Principal Investigator

#### **DISTRICT OF COLUMBIA**

Washington Regional AIDS Program †  
Fred Gordin, M.D. Principal Investigator  
CPCRA Group Leader

#### **FLORIDA**

Comprehensive Care Center: Fort Lauderdale ‡  
Michael Sension, M.D., Principal Investigator

#### **ILLINOIS**

AIDS Research Alliance: Chicago †  
Roberta Luskin-Hawk M.D., Principal Investigator

#### **LOUISIANA**

Louisiana Community AIDS Research Program †  
David Mushatt, M.D., Principal Investigator

#### **MICHIGAN**

Henry Ford Hospital †  
Norman Markowitz, M.D., Principal Investigator

Wayne State University †  
Lawrence Crane, M.D., Principal Investigator

#### **MINNESOTA**

Hennepin County Medical Center ‡  
Keith Henry, M.D., Principal Investigator

#### **NEW JERSEY**

New Jersey Medical School: Newark ‡  
Jerrold Ellner, M.D., Principal Investigator

North Jersey Community Research Initiative: Newark †  
George Perez, M.D., Principal Investigator

Southern New Jersey AIDS Clinical Trials: Camden †  
John Baxter, M.D. Principal Investigator

#### **NEW YORK**

Bronx AIDS Research Consortium †  
Edward Telzak, M.D., Principal Investigator

Harlem AIDS Treatment Group †  
Wafaa El-Sadr, M.D., Principal Investigator  
SMART Study Co-Chair

Westchester Medical Center: Valhalla ‡  
Harold Horowitz, M.D., Principal Investigator

#### **OREGON**

Research and Education Group: Portland †  
James Sampson, MD, Principal Investigator

#### **PENNSYLVANIA**

Philadelphia FIGHT †  
Ellen Tedaldi, M.D., Principal Investigator

#### **TEXAS**

Houston AIDS Research and Treatment †  
Roberto Arduino M.D., Principal Investigator

#### **VIRGINIA**

Richmond AIDS Consortium †  
Evelyn Fisher, M.D., Principal Investigator

### **PARTICIPATING INTERNATIONAL CENTER**

#### **AUSTRALIA**

National Centre in HIV Epidemiology and Clinical Research ‡  
Sydney, Australia  
David Cooper, M.D., Director  
Jenny Hoy, M.D., Principal Investigator

† CPCRA Units

‡ SMART Associate Sites