



# Update

## **EMBARGOED UNTIL**

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Laurie K. Doepel  
301-496-5717

## **NIAID FUNDS MAJOR STUDY OF HIV INFECTION AMONG HETEROSEXUALS**

Heterosexual men and women who are not intravenous (IV) drug users but who are at high risk for HIV infection will be the focus of a major new epidemiology study announced today by the National Institute of Allergy and Infectious Diseases (NIAID). NIAID has awarded three contracts for a collaborative, prospective study of the transmission and natural history of human immunodeficiency virus (HIV) infection among some 2,000 heterosexuals. Study centers in Newark, New Jersey, and Brooklyn, New York, and a data coordinating center in Ann Arbor, Michigan, received the contract awards. First-year funding for the 5-year contracts totals nearly \$4 million.

Dr. Anthony S. Fauci, director of NIAID, emphasized the importance of this study for designing more effective strategies to prevent and treat HIV infection. Although only 4 percent of all adults diagnosed with AIDS since reporting began acquired the disease through heterosexual contact, this mode of transmission accounts for 30 percent of all AIDS cases in women. Heterosexual HIV transmission usually occurs by sexual contact with an IV drug user.

The study sites were chosen in part because they are located in inner-city areas populated by large numbers of HIV-infected drug users, a potential reservoir of infectivity for heterosexuals. Principal Investigator Stanley H. Weiss, M.D., chief of AIDS and Retroviral Epidemiology in the Department of Preventive Medicine at the University of Medicine and Dentistry of New Jersey (UMDNJ)-New Jersey Medical School in Newark, will head one study center. Co-Principal Investigators Sheldon H. Landesman, M.D., Associate Professor of Medicine, and Jack A. DeHovitz, M.D., M.P.H., both of the State University of New York-Health Science Center at Brooklyn (SUNY-HSCB), will head the second study center. The data coordination center will be headed by Principal Investigator Richard Cornell, Ph.D., of the University of Michigan School of Public Health in Ann Arbor.

The overall goals of the study are to determine

- the natural history of HIV infection in non-homosexual women and men who have no history of intravenous drug use;
- sexual and other behaviors associated with the transmission of HIV in such a population;
- biological and environmental cofactors associated with the acquisition or severity of the expression of HIV infection in such a population.

Among the factors to be evaluated for their influence on the transmission and course of HIV infection are the presence of other sexually transmitted diseases, co-infection with HTLV-1 or other retroviruses, infectivity of the source case, and use or non-use of condoms. In addition, the investigators will study the natural history of HIV infection by following patients clinically while simultaneously assessing their immune system functioning.

Neurologic, neuropsychologic, and neuroradiologic testing of some seropositive study participants will be carried out to determine how HIV infects the brain and the nervous system. Also, the progress of HIV infection in heterosexuals will be compared with similar data accrued from people who have acquired HIV infection through other routes, for example, intravenous drug users. In addition, the study will assess educational intervention strategies.

Those considered at high risk for HIV infection and therefore eligible to be enrolled in the study include 1) heterosexuals with a history of multiple sexual partners (defined as an average of 10 or more sexual partners per year); 2) those with a history of sexually transmitted disease(s) within the past 5 years; 3) those with known sexual contact with person(s) considered to be at high risk (or engaging in high risk behavior) for HIV infection; 4) those concomitantly infected with or exposed to other fungal, viral, retroviral, bacterial, or parasitic infections, cofactors that might increase the risk of acquiring or the severity of HIV infection.

The New Jersey study will recruit a cohort of 1,000 heterosexual men and women through AIDS counseling and testing sites set up by the state in three health facilities in northern New Jersey. In addition, infectious disease specialists at these facilities and at the UMDNJ-University Hospital in Newark will refer patients to the study team.

Unlike the New Jersey study, the New York study will principally focus on recruiting heterosexual women. However, a select group of men who are sexual partners of HIV-positive and HIV-negative female participants will be asked to enroll. Also, steady male sexual partners of women who are initially HIV seronegative and then seroconvert will also be assessed. A cohort of 1,000 participants for the New York study will be recruited through an AIDS testing site, through sexually transmitted disease, drug treatment, and family planning clinics in the Brooklyn area, and through the sex partners of the AIDS population the study center serves. Strict patient confidentiality will be observed in both study centers.

This collaborative project is modeled after a similarly designed NIAID-funded study conducted in cohorts of homosexual men (the Multicenter AIDS Cohort Study, or MACS).

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