

UM to Lead New NIH-Funded Study of Aging of Men and Women with HIV

The National Institutes of Health has awarded University of Miami researchers \$14 million for an ambitious seven-year project that will keep the Miller School of Medicine at the forefront of cutting-edge HIV research. The research will track cardiovascular and pulmonary disease as well as other non-infectious conditions that people with HIV – both women and men – experience as they age.



From left, Dr. Maria Alcaide, Dr. Margaret

Fischl, and Dr. Deborah Jones Weiss.

Principal investigators Margaret Fischl, M.D., Deborah Jones Weiss, Ph.D., M.Ed., and Maria Alcaide, M.D., are working with an interdisciplinary team of HIV experts at UM and 12 other sites around the United States to launch the project.

“We really felt it was important to look at differences between men and women, that it would give us additional information about how this impacts individuals with HIV infection,” said Dr. Fischl, professor of medicine at the Miller School. The study “would allow us to do that comparison when no one else has been able to do that.”

Several elements are coming together to make this happen. Investigators of an ongoing study called the Women’s Interagency HIV Study (WIHS) will join forces with researchers for the longitudinal Multicenter AIDS Cohort Study (MACS), which evaluates men who have sex with men and heterosexual men with multiple partners, for example.

In addition to exploring differences between sexes, the MACS/WIHS Combined Cohort Study aims to understand and reduce the impact of comorbid conditions among people with HIV infection.

Multidisciplinary Approach

The National Heart, Lung, and Blood Institute, part of the NIH, is the steward of this project involving 15 NIH institutes. The scope of the project is multidisciplinary, because some participants might also be at higher risk for infection with hepatitis C and B, herpes simplex or human papilloma viruses, as well as mental illness, diabetes, renal

failure, and musculoskeletal disorders.

The Miller School researchers will play a critical role in the study. “We’re of particular interest to the NIH this go-around because we’re one of five Southern sites,” Dr. Fischl said. A rise in the incidence of HIV, particularly among young and diverse Americans, is hitting the Southeast the hardest.

In fact, the [latest report](#) from the Centers for Disease Control and Prevention places the Miami-Fort Lauderdale-West Palm Beach metropolitan area at #1 for the highest prevalence of new HIV diagnoses nationwide. “I’m concerned that after conducting HIV research for 30 years, we continue to see a high number of people with newly diagnosed HIV infections,” Dr. Fischl said.

“We’re at the forefront in terms of the burden of HIV, but we are also at the forefront in terms of the fact that we are responding,” said Dr. Jones Weiss, a professor of psychiatry and behavioral sciences at the Miller School.

Nearly half of the men and women with HIV infection in the United States are racial/ethnic minorities living in the South. Unlike many other sites nationwide, the Miller researchers have access to a large Hispanic population.

The Miller School component will re-consent and enroll the 132 women currently in the Miami WIHS.

“Those women who participated in WIHS at the University of Miami over the last seven years will continue to be part of the combined cohort study,” said Dr. Alcaide, associate professor of clinical infectious diseases at the Miller

School. Women are underrepresented in HIV research. This study aims to facilitate gender comparisons, and will address issues related to women.

Adding Men to the Equation

Another goal is to enroll men from the local community for the first time. Investigators plan to recruit and retain at least 270 total participants, including people with HIV infection and those at risk. The diversity of the South Florida population is a plus. “Miami has some of the highest rates of racially and ethnically diverse gay men being infected,” Dr. Jones Weiss said. “Miami gives us the opportunity to bring people into this cohort study who are not available in large numbers anywhere else.”

The potential role of the microbiome, or population of microbes in each person, on HIV-related comorbidities is another focus of the research. An imbalance in the microbiome has been associated with HIV pathogenesis, heart disease risk, weight gain and other aspects of health, and any differential effect on people with HIV remains unknown.

“The study will move forward the field of microbiome research and its impact on HIV pathogenesis and other comorbidities,” said Dr. Alcaide, who also leads the study’s pathogenesis working group.

Expected New Discoveries

New discoveries regarding neurocognition are another likely outcome of the study. Although clinicians see fewer cases of HIV-related dementia in the modern era of HIV treatment, “we do see other elements of neurocognitive function that are

going down over time,” Dr. Jones Weiss said.

Advances and new discoveries made by the researchers will ultimately be included in clinical practice guidelines to help physicians optimize treatment of people with HIV, Dr. Fischl said.

Collaborating Research

The research will be open, transparent and collaborative. Locally, the team is working with the City of Miami, including the Department of Health, and the Miami Center for AIDS Research, the AIDS Institute, and other multidisciplinary researchers across the Miller School campus.

“One of the things we’re hoping to do is combine efforts with the [new CHARM Center](#) (Center for HIV and Research on Mental Health), which will be targeting HIV and mental health,” Dr. Jones Weiss said. “We hope to leverage and build on each other’s skills and access to patients. We’ll be looking at how best to address mental illness in our patients.”

Data and tissue and blood specimens will be available to other HIV researchers. “Investigators from all over the country have contacted us, saying they want to work with the team and run their own science,” Dr. Jones Weiss said.

“It’s critical from the NIH’s point of view that the data is accessed and used to answer additional research questions,” Dr. Fischl said. As an ongoing research project, now spanning decades, questions will continue to emerge over time.

Dr. Fischl, who has served as principal investigator for the WIHS study for seven years, now takes the helm of the Miami

site for the Combined Cohort Study with Drs. Alcaide and Jones Weiss. Dr. Jones Weiss sees that as a major advantage. “Margaret Fischl has really been one of the leaders in this field since the beginning of the epidemic. Her contributions are immeasurable. It’s a true testament to her dedication that she is continuing to study HIV after all these years.”

The investigators are finalizing the protocol for what they hope to accomplish, at least in the first two years. Institutional review board (IRB) approval is also in the final stages.

“We are starting to consider screening candidates for the study, so when the protocol opens, we can move quickly at enrolling patients,” Dr. Fischl said. Once all the forms are completed and the IRB has approved, “we will be able to start enrolling patients. I anticipate that will happen late this year or early next year.”

The Miami site is creating a website with additional information on the study, including how to refer potential candidates for consideration. The NIH National Heart, Lung, and Blood Institute also provides [more information](#) on the project.