

# The WIHS Woman



## The Connie Wofsy Women's HIV Study

### Changes for Visit 35

*By Claudia Ponath, Field Manager*

The last 6 months have flown by very quickly. It seems the older I get, the faster time goes by, in spite of my best efforts at slowing down. Below is a description of what you can look forward to at your next WIHS visit:

#### *What's new?*

There are two new questionnaires this visit. Both will be administered one time only. One of the questionnaires asks detailed questions about your, your parents and your grandparents racial and ethnic background (see article on ancestry on page 5). Many of our participants have a diverse ancestry, and your ancestry may play a role in both your susceptibility to certain illnesses as well as your response to certain medications. The other questionnaire will be asked only of our HIV negative participants. It's about women's knowledge of and interest in new HIV prevention methods and asks specifically about Tenofovir Vaginal Gel and pre-HIV exposure prevention methods.

We will start a new sub-study called the Muscularskeleton (MSK) Study. This is an extension of the metabolic study and there is an article in this newsletter about it, so I'll only say that Heneliaka will coordinate it and that if you are eligible and decide to participate, we will ask you to consent at your core visit.

There are some changes to the blood draw protocol: WIHS investigators would like to collect some additional blood from certain groups of participants whose blood specimens are in great demand. There are 3 groups of participants that will have extra tubes drawn. One group are the "elite controllers", that is HIV-positive women who have an undetectable viral load without being on any HIV medications. The second group is HIV-positive women who have never taken HIV medications and are starting them for the first time. The third group is HIV-negative women who become HIV-positive – fortunately there have been very few HIV seroconversions in the WIHS and we hope it will remain that way.

With your consent, we will also collect addi-

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tional tubes of blood from women in the new MSK study. Finally, we'll be collecting blood from some women to look at the number of CD4 and CD8 cells in relation to Human Papilloma virus (HPV) and cervical dysplasia.

### *What's continuing?*

Please **bring your medications in their original bottles, your medi-set, or a list of the medications you have taken since your last visit to your study visit. For those of you on HIV meds, we'll also need the dose information.** Bringing this information to your interview is incredibly helpful, and it will make your interview go more smoothly. And if you have been bringing this information, please continue to bring it. Both you and your interviewer will be glad you did.

Please **fast (don't eat or drink anything, except water, for at least 8 hours)** before your WIHS core visit. This is crucial for getting an accurate test result for your cholesterol, lipids, and glucose. These blood tests are important markers for diseases that affect women, including diabetes, heart disease, and high blood pressure.

If you are HIV-positive, we will ask your permission to cut a small amount of your **hair** (about 20 strands). These hair samples are being tested for levels of HIV medications. So far, we have looked at levels of Lopinavir and Raltegravir and found that levels of those drugs in hair are a very strong predictor of your response to HIV treatment.

The **Neuro-cognitive component** of the WIHS will continue during visit 35. We completed the first round in visit 33, and started up again at visit 34, meaning if you did the neuro-cognitive assessment 2 years ago, we will ask you to do it again this visit. The neuro-cognitive tasks are administered verbally, using paper and pencil, and using a pegboard.

You will be asked to read words, recognize shapes, solve problems, memorize things and engage in other mental tasks. Some of the tasks will be familiar from previous WIHS visits and some will be new. The purpose of this component is to look at cognition – that is mental processes such as memory and learning. It takes about an hour, and we reimburse you an additional \$20 for your time and effort to complete it.

The **CIDI study** will continue during visit 35. All HIV-positive study participants are eligible to participate unless you already completed the CIDI during visit 34. The purpose of this study is to learn about women's emotional health and well-being, both now and when they were children. It consists of an interview only, which will be done by either Karen in the East Bay or Alyson in San Francisco. The reimbursement is \$40.

The **Cardiovascular study** at the San Francisco VA hospital will continue during visit 35 for those of you who are enrolled in this substudy. The visit involves an ultrasound of your neck to look at possible blockages in the artery and the reimbursement is \$40. Your interviewer will let you know if you are eligible and Heneliaka will coordinate this study visit.

The **Pulmonary Study** will continue during visit 35 and consists of a blood draw, interview, a lung function test and a chest CT scan. All procedures take place at the UCSF Mount Zion campus. The study visit takes about 3 hours and you will be reimbursed \$60. Heneliaka is coordinating this study and your WIHS study interviewer will determine if you are eligible. We have reached our target number and are now doing only follow-up visits on the enrolled women. Most, but not all, women who

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had an initial visit will be asked to come back for a follow-up visit.

The **Fibroscan Study** will continue during visit 35. The Fibroscan is an ultrasound scan of your liver to check for stiffness (also called “Fibrosis”). This study is being done to understand how body fat and metabolism relate to HIV, Hepatitis C, or obesity and how this affects the health of your liver. The study visits take place at Moffitt hospital on the Parnassus campus in San Francisco. The reimbursement is \$40 and Alyson, the study coordinator, will determine if you’re eligible. If you had your visit last fall, you will likely get a call for a follow-up visit, as the 6 month follow-up phase of the study is about to start.

The **Pharmaco-Kinetic (PK) study** will continue during visit 35 and women who are taking Isentress (Raltegravir) are eligible to participate, if they haven’t already. The PK study looks at factors that influence how HIV drugs are metabolized in your body. For this study, eligible participants bring their medications to the hospital. They have their blood drawn once before they take their dose and then 11 times after they take their dose over the course of 12 hours. It takes place at Moffitt hospital on Parnassus in San Francisco. The reimbursement is \$150 and Heneliaka coordinates this study.

**Abbreviated visits** will continue for women who are unable to have an in-person core visit. If you do have an abbreviated visit, we will now ask you a few short questions about pregnancies.

For women undergoing colposcopy, we will continue to ask if you want to donate tissue to the **AIDS and Cancer Specimen Resource (ACSR)**. Women do not need to have cancer or

HIV to enroll in this sub-study. Women who are eligible and wish to donate tissue to the bank will have an extra biopsy, oral rinse, and one tube of blood collected for this study at the time of their colposcopy examination.

### *What’s gone?*

The examination of your feet and ankle reflexes is on break for this visit, as are the breast and uterine exams. These will be back for the next visit. We have completed the administration of the family and personal medical history questionnaire, and thank you all for answering those questions.

### *In conclusion*

We would like to thank all of our participants for their contribution to this very important study: the participants who enrolled in 1994 and 1995 and have been coming to study visits faithfully for over 17 years; the participants who started in 2001, who have now been attending study visits for over 10 years; and our new recruits, whom we hope to see for many years to come. We look forward to seeing you all at your next WIHS visit, and your next sub-study visit and the next CAB meeting.



## WIHS Open Enrollment in 2011

*By Nancy Hessol, Project Director*

WIHS recruitment update: we are currently recruiting new participants into the WIHS. Starting in January 2011, we began recruiting HIV-positive women and **NOW** we are also recruiting new HIV-negative women. Women who meet our inclusion criteria may be eligible to join our research study.

Here are some statistics on our current recruitment efforts as of 9/8/11 for the HIV-positive women. After a brief telephone screening, we saw 83 women for an in-person screening evaluation of whom 21 did not meet our eligibility criteria. Of the remaining 62, 42 women have had their baseline visit and have joined the WIHS, another 14 women are awaiting their baseline visit, and 6 women are waiting for medical record review.

We will be recruiting during 2011 and our target number of women is 62 HIV-positive and 26 HIV-negative women. Therefore any **HIV-positive woman who is 30 to 49 years old** and interested in getting screened for enrollment should contact us right away. In addition, **HIV-negative women who are between the ages of 35-60** and have had multiple sex partners in the past year or injected drugs should contact us now. Please see the flyers on the back page of this news letter for more information.

If you are one of our newest recruits, I warmly welcome you into our study and hope you enjoy the experience and stay with us for many years to come.



## CAB CORNER



*By Heneliaka Jones  
(a.k.a. Ladybug)*

Hello Ladies,

I hope you enjoyed the summer! We had a wonderful July CAB meeting in San Francisco and, although we didn't have warm Mediterranean weather, we did have a delicious Mediterranean meal. Dr. Deborah Cohan gave an informative presentation on gynecological issues. Not surprising, CAB members asked a lot of questions about menopause and ways to treat common symptoms such as hot flashes and night sweats. Dr. Cohan suggests that you allow menopause to take its course and avoid using medicinal treatments, when possible. She offered practical advice, such as, keep a fan by the bedside and/or open the window during the nights. Sleep in light clothing, and don't sleep under a lot of covers. Changes in your diet might also help to lessen these symptoms. For those of us that have not experienced menopause yet and want to prepare for the inevitable, then talk to your mom. Most women start menopause around the same age as their mothers and tend to have the same symptoms.

Another topic we talked about was the Human Papillomavirus, also known as HPV. HPV is reported to be the most common Sexual Transmitted Infection (STI), according to the Center of Disease Control (CDC). There are also many strains of the virus. One thing to know ladies, men usually don't show any symptoms of the virus! If you have HPV don't be so quick to blame your current sex partner. It doesn't necessarily mean that he has cheated on you. A person can have HPV for many years, and your current partner may not be the person who infected you.

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After Dr. Cohan's presentation, there were a lot of announcements and then we played one of our favorite games "Get to know your fellow CAB member". All in all it was a delightful afternoon and I look forward to seeing more new faces at our next CAB meeting.

One final note, please prepare your appetites and get a jump start on the Holiday season because we are going to have our End of the Year Holiday Retention Party in December! We don't have a final date yet, but more information will come in the mail.

Best wishes for the fall season.



## New WIHS Questionnaire on Ancestry and Race

*By Niloufar Ameli*

The US population is composed of many individuals whose ancestors have come from more than one geographic area, such as African and Hispanic Americans. While individuals in these "mixed" groups might self-report into a single ethnic/racial category, their actual ancestry genetically can be mixed. For example, self-identified African-Americans show anywhere between 0 and 80% European ancestry and self-identified Hispanics show anywhere between 0 and 90% Native American ancestry, when measured genetically. Populations with different ancestral backgrounds may carry different genetically determined characteristics that are important for the development of disease and how it is treated.

Currently, there are two main approaches used to approximate a person's genetic heritage, (a) self-reported race and ethnicity, which may capture cultural and common environmental influences as well as ancestral background, and (b) measurement of specific genetic markers that are known to differ across geographic groups (for example, between Africans and Asians). The WIHS has undertaken both approaches in order to characterize the racial and ethnic background of the study participants. However, the previous data collection questionnaire was very limiting, because it did not allow participants to self-identify into multiple racial and ethnic categories. As a result 652 (17%) of the participants have selected the "Other" or "Other Hispanic" category as their race/ethnicity.

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To identify mixed heritage, during visit 35 we will administer a questionnaire and collect data on race and country of birth of the participants, their parents, and grandparents. This new questionnaire will allow the participant to select multiple racial and ethnic categories to describe her ancestral background. This will provide a more accurate definition of “race” for data analyses and scientific report. We will also evaluate how well these more detailed definitions of race and ancestry match the genetic markers.



## New WIHS Study of Bones and Muscles

*By Dr. Phyllis Tien*

This fall we are starting a new 5-year study to understand the role of menopause on the health of your bones and muscles. Studies from the WIHS show that HIV-infected women have lower bone density than HIV-uninfected women. However, it is not clear what happens to the bones during the menopausal transition period. For this new NIH-funded study, we are targeting the HIV-positive and HIV-negative women who participated in the Metabolic study, plus we hope to enroll the women who recently joined the WIHS.

Similar to the Metabolic Study, we will perform a DXA scan (but not the glucose tolerance test). The DXA scan will measure the amount of fat in different parts of the body, the density of the hip, spine, and arm bones, and assess whether there is a fracture (broken bone) in your back. The DXA scan will also give us information about whether you have osteoporosis (or fragile bones). However, it is not com-

pletely clear whether a finding of osteoporosis is the best way to determine if you are at risk for a fracture in the future. That is why for this study, we will also do a CT scan of your hip and spine to look at the structure of your bones in these areas. This may give us more information about your risk of fracture. The CT scan will be done in women who have recently begun menopause or are about to begin menopause.

If you are eligible and agree to participate, we will also measure your balance while standing, the curvature of your back, your hand, back and leg strength, and how fast you can walk. In addition, a few extra teaspoonfuls of blood will be drawn at the Core visit to measure immune cells and proteins that might worsen bone density and structure.

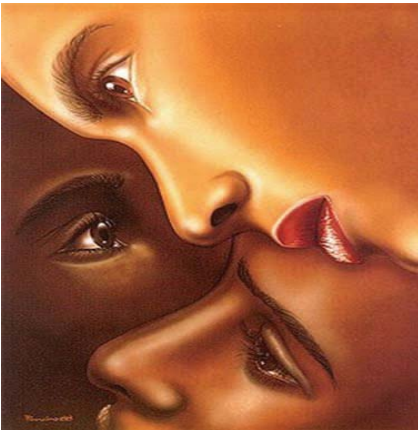
The DXA scan, CT scan, and these other measurements will be done twice 2 years apart. You will be reimbursed \$25 for doing the DXA scan, \$50 for doing the CT scan, and \$10 for doing the other measurements.

Some women may also be asked to do a MRI scan to measure the amount of fat in other parts of the body including the belly, liver, and bone marrow. If you agree to the MRI, then you will be reimbursed an additional \$50.

We really hope you consider being a part of this exciting new study. The results from this new study will give us important information on what happens to bones and muscles as the transition to menopause begins.

Finally, we also want to thank all the women who participated in the Metabolic Study. Your past participation made funding for this new study possible.





# Join the WIHS

## **What is the WIHS?**

**It is the largest study of HIV among women in the US. The study is being conducted by researchers at the University of California at San Francisco (UCSF) and includes women who are living with HIV and women who do not have HIV.**

## **What will happen if I join?**

**You will have a study visit twice a year including an interview, physical exam and laboratory tests. Study visits will take place in our San Francisco and East Bay Clinics. You will receive \$50 for each study visit, your travel will be compensated, and food and thank-you gifts will be available. All information collected is confidential.**

## **Who can join?**

**If you are an HIV-positive woman and are 30 - 49 years old. Participants will include women of all backgrounds to represent the diversity that the Bay Area is known for.**

## **How do I join WIHS?**

**Call to speak with a member of the WIHS staff. They can determine if you are eligible for the study and answer your questions.**

**PLEASE CALL 415-353-9797 or 510-869-6972**

**Spaces are limited!!!**

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If you are an HIV negative woman and are 35 - 60 years old. Participants will include women of all backgrounds to represent the diversity that the Bay Area is known for.

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