

## **Letter from the Principal Investigator**



reetings for the Holidays and thank you once again for another successful and productive year for SHARE. With your contributions of time, effort, and support, we have continued to fulfill our mission of helping not just the AIDS research effort, but the health of people everywhere, whether HIV-positive or not. The U.S. Office of AIDS Research (OAR) has listed conditions associated with living with HIV on a long-term basis as one of the high-priority areas of HIV/AIDS research for the future. SHARE is excellently positioned to contribute to this area of research, because we include men living with HIV as well as a roughly equal number of similar men who do not have HIV. The HIV-negative men provide the essential comparison group we need in order to understand what happens over time that can be attributed to being HIV-positive and receiving anti-HIV medications. Studies we are

conducting on the health of the heart and cardiovascular system, kidneys, brain and nerves, gastrointestinal system, and, as I will describe below, the lungs all are focusing on these high-priority questions. Because the long-term health of people living with HIV is such an important area of research, it now appears that the National Institutes of Health (NIH) will be renewing support of SHARE and its parent study, the Multicenter AIDS Cohort Study

(MACS), for another round of 5 years, beginning in 2019. The National Institute of Allergy and Infectious Diseases (NIAID), our main funding institute, told us they would not be supporting us after 2019. The NIAID made this decision because they believed that their highest priorities were an HIV vaccine and an HIV cure. However, other institutes of the NIH, which had not provided major (or, in some cases, any) funding for SHARE and the MACS have realized that our cohort is very important for their research missions. It is these other institutes in the NIH that will be supporting SHARE and the MACS after 2019. This is especially true for the National Heart, Lung, and Blood Institute (NHLBI). This past year, NHLBI has started to provide funding to SHARE and the MACS, so that we can now perform clinical tests of heart and lung function as part of our regular study visits.

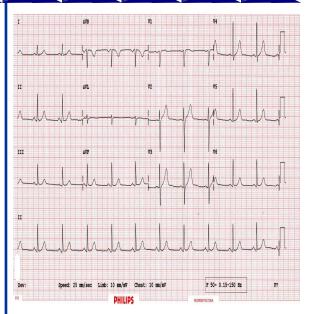
Continued on page 8

Inside this issue:	
New Study	2
Study Updates	3-5
News from Whitman-Walker Health	6
SHARE's Upcoming Studies	7
Community Advisory Board Mem- bers Needed	8

# New Study - MACS Electrocardiogram and ZIO patch Study

The overall purpose of the study is to better understand cardiovascular consequences of HIV infection and its long-term treatment. The electrocardiogram study looks for abnormalities in the electrical system of the heart. The Ziopatch study investigates whether or not heart rhythm problems occur more frequently in HIV-infected compared to -uninfected men and will try to identify risk factors for these abnormalities. In so doing, we may be able to develop strategies to prevent the occurrence and progression of heart rhythm problems by addressing the risk factors proactively.

The study started on October 1, 2016, and the testing is projected to continue until March 31, 2017. As of November 12th, there have been 464 participants across all the MACS sites with 136 from the Baltimore/Washington DC SHARE sites. We are grateful for your participation and dedication. We look forward to providing study updates in future newsletters





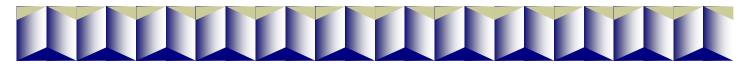
## How are we doing?

In exchange for the time that you have continued to give us over the years, we want to do everything that we can to make your visits as comfortable, productive, and efficient as possible. We want to hear about your visit experience – the good, the bad, and even the ugly. Please contact Dr. Margolick (410) 955-1436 or jmargol1@jhu.edu) or Jacquett Johnson at (410) 955-4912 or jjohns20@jhu.edu with any comments you may have.

## **Study Updates**

The following studies were included as new studies in the last SHARE newsletter. Here, we present updates on those studies.

	MACS Heart Health Study 3	MACS GUT Microbiome Heart Study	Subclinical Myocardial Abnormalities in MACS/ALIVE/WIHS by Cardiac MRI (SMAsh-CMR)	SHARE Energy Expenditure Study (SEES)
Purpose of the study	To determine whether atherosclerosis (narrowing, blockage, or hardening of the arteries) increases faster in persons with HIV infection. Also studying how body fat and inflammation relate to heart disease.	To determine whether bacteria in the gut affect health, including atherosclerosis, in men with and without HIV infection. Also, how the gut bacteria may change inflammation that can lead to heart disease.	To learn more about how well the heart muscle is working in person with and without HIV infection.	To determine the effect of HIV infection on energy expenditure (metabolism) and physical function with aging.
Eligibility for the study	Approximately 200 men who had a heart CT scan with contrast between 2010 and 2013	100 men who participated in the Heart Health Study and had a heart CT scan between 2010 and 2013	400 total from all 4 MACS sites — 110 (72 HIV+ and 38 HIV-) from SHARE, 40- 60 years of age	200 men (100 HIV+; 100 HIV-), 40 years of age or old- er, who weigh less than 300 pounds
Procedures	Blood draw, CT scan of the heart (with contrast dye), abdomen and thigh	Questionnaire, and one stool sample	Blood draw, questionnaires, cardi- ac Magnetic Reso- nance Imaging (MRI) with contrast dye, electrocardiogram, and Ziopatch (continuous EKG monitor for 14 days)	DEXA scan, resting energy expenditure assessment (breath analysis), walking energy expenditure assessment (breath analysis), and a physical activity assessment
	\$75 for completing all study procedures	\$20	On the day of the study visit, \$75 plus a \$10 Hopkins meal card, and \$25 when the ZioPatch is returned.	\$50 for completing all study procedures, plus up to \$100 in document- ed travel expenses.
Men enrolled as of November 30, 2016	84 HIV+ and 74 HIV-	41 HIV+ and 47 HIV-	58 HIV+ and 39 HIV-	47 HIV+ and 48 HIV-
SHARE Study Coordinators	Mr. Lance Ambrose (410) 955-7090 or (410) 955-5318	Mr. Lee Savoy (410) 955-7090 or (443) 287-3769	Mr. Lance Ambrose (410) 955-7090 or (410) 955-5318	Ms. Robin Lincoln 410) 955-7090
SHARE Investigators	Principal Investigator: Dr. Wendy Post	Principal Investigators: Drs. Wendy Post and Cynthia Sears; Co-Investigator: Dr. Joseph Margolick	Principal Investigator: Dr. Wendy Post	Principal Investigator: Dr. Jennifer Schrack



## **Study Updates**

## **Healthy Aging among Men with and without HIV**

The purpose of this research study is to identify and measure the resilient patterns of life experiences among men with and without HIV and how these patterns promote healthy aging. We are asking you to complete a survey over the next 6 study visits (we are currently in the 2nd study visit of data collection). There will be some core questions that you will be asked every study visit to identify changes in these patterns over time, but at each visit we will ask new 'cutting edge' questions as well. We appreciate dearly your participation in this important work.

Ron Stall, PhD Principal Investigator Michael Plankey, PhD Co-Investigator

### **Hearing 4 Study**

SHARE has received funding to conduct additional hearing assessments (called central auditory processing tests) for a subset of participants who completed previous hearing testing either at Johns Hopkins University Hospital or Medstar Georgetown University Hospital. In our earlier study we found increased hearing loss among HIV+ compared to HIV- SHARE men. We are hopeful that this additional testing will help to explain these differences.

We have completed testing of the eligible men in Washington, DC. Recruitment of the Baltimore men will begin in mid-December. Please be on the lookout for a recruitment letter from us. Thank you.

Michael Plankey, PhD Principal Investigator

## **More Study Updates**

## SHARE Energy Expenditure Study (SEES)

The purpose of this study is to learn more about potential differences in energy expenditure and physical activity between HIVinfected and -uninfected men with aging. other studies in the general population, energy expenditure at rest and during walking has been shown to predict an increased risk of mobility decline with aging. Enrollment for this study is ongoing, with 93 men enrolled in Baltimore and Washington, DC to date. We would very much like to increase enrollment in this study. If you are interested in participating, please contact Ms. Robin Lincoln at (410) 955-7090. Questions about SEES should be directed to Dr. Jennifer Schrack, Principal Investigator, at (410) 502-9328 or ischrac1@ihu.edu

Preliminary results from SEES were presented at the  $7^{\text{th}}$  annual Workshop on HIV & Aging in Washington D.C. in September. This analysis used data from 75 men aged 40 and older (40 HIV+ and 35 HIV-) who underwent

resting metabolic rate testing and body composition analysis via DEXA. Results indicate that those infected with HIV had a higher metabolic rate by approximately 87 calories per day. This difference was greater in HIV-infected men who were also diabetic and/or had decreased kidney function. Also, those who were not virally suppressed tended to have a higher metabolic rate than those who were suppressed.

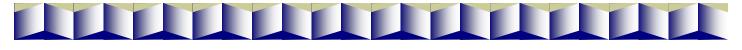
Together, these results indicate that those aging with HIV appear to have a higher metabolic rate than those aging without HIV, and that metabolic complications such as diabetes and reduced kidney function tend to intensify this effect. More participants are needed to further explore the potential pathways contributing to these results.

## **Liver Health Study**

We are continuing to recruit SHARE participants to this study, which aims to understand what factors lead to liver disease in men with and without HIV infection. We are sending letters to men who are eligible from both the Baltimore and Whitman Walker clinics. Liver health is being determined using an FDA-approved test called the Fibroscan, a noninvasive procedure which uses ultrasound waves to evaluate the liver.

To date, 44 men have had the Fibroscan (38 in Baltimore and 6 from Whitman Walker). We are planning to scan an additional 200 men. If you are interested in this study and have not heard from us, please contact Lee Savoy at 410-955-7090 or via email at Isavoy1@jhu.edu.

Chloe Thio, MD Principal Investigator Michael Plankey, PhD Co- Investigator



### **News from Whitman-Walker Health**

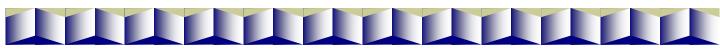
#### News from Dr. David Hardy and Whitman Walker Staff

Whitman-Walker Health (WWH) is continuing to change and grow. With this change, the SHARE clinic at WWH will be moving in 2017. Dr. David Hardy, WWH SHARE Principal Investigator, and Whitman-Walker executive staff have been busily working to secure a temporary location for the Clinical Investigations Department. WWH, in partnership with Fivesquares Development, has secured approval from the Historic Preservation Review Board for its mixed-use redevelopment on 14th Street. The redevelopment will retain the historic Elizabeth Taylor Medical Center at 1701 14th St NW as well as the mid-block Belmont Garage building at 1711 14th St. Alongside those, the new structure will include a 160k square-foot mixed-use building with four floors of apartment units, 51k square-feet of office and 16k square-feet of ground-floor retail. WWH will occupy 30k square-feet of the office space and plans to create a community gathering space on the ground floor. With the remaining retail space, the developer plans to bring in a recognizable restaurant as well as some boutique shops.



Construction is slated to begin in the third quarter of 2017 with an expected delivery in late 2019 or early 2020. We believe we will be relocating to medical office space in lower Dupont Circle area on 19th St NW.

The new temporary space does have parking available. More details of the relocation will be forthcoming.



## **Upcoming Studies**

#### **PULMONARY STUDY**

During Visit 67, which begins on April 1, 2017, SHARE will be conducting a new test of lung function on all study participants. This test is called Pulmonary Function Testing (PFT). The purpose of the test is to assess the main functions of the lung; both the amount of air inhaled and the rate of air movement are important factors that determine how well the lungs are working. These tests of lung function will be done with support we have obtained from the National Heart, Lung, and Blood Institute (NHLBI). NHLBI has recently increased its support of SHARE and the other centers of the Multicenter AIDS Cohort Study (MACS), for which we are very grateful.

#### What Does The Study Involve?

If you agree to the test, you will be asked to breathe in and out of a tube connected to a device that measures the volume of air that you breathe in and out with each breath, and the speed with which you do it. The PFT should take about 45-50 minutes. It will replace the electrocardiogram and heart monitor (Ziopatch) testing that is now being done at Visit 66.

#### What We Are Measuring

In order to bring inhaled oxygen into the body, the oxygen must cross the lung membranes that separate air in the lung from blood in the blood vessels in the lung. This crossing process is called diffusion. Carbon dioxide leaves the body by the reverse process, i.e. diffusion from the lung blood vessels into the air spaces of the lung. The ability of the lung to permit diffusion of oxygen into the body and carbon dioxide out of the body is called the pulmonary diffusion capacity, and this is also a very important measure of lung function. The difference between the carbon dioxide levels in the inhaled and exhaled air reflects the amount of carbon dioxide that diffused into the body, and thus the pulmonary diffusion capacity. We will also measure this capacity during your SHARE visit.

Results of the PFT can be shared with you and, with your written permission, with your health care provider. We would be happy to answer any questions you may have about the PFT- contact Dr. Margolick at <a href="margoli@jhsph.edu">jmargoli@jhsph.edu</a> or 410-955-1436.

#### **MOUTH STUDY**

The purposes of the study are to better understand how certain behaviors (like smoking) and other factors affect rates of infection with oral human papillomavirus (HPV) and how likely this infection is to persist over time, and to learn more about infection. If you choose to participate, this virus will be measured in cells from oral rinse, saliva, blood, and urine samples you provide..

#### What Does The Study Involve?

If you participate in the study, we will ask you to swish saline (salt water) in your mouth and then spit it into a cup. Cells from these rinses will be tested for HPV DNA. We will also collect saliva and urine samples. We will ask you to take a short survey about behaviors we think might be related to risk of having oral HPV infection. We will ask you to participate now and then once each year for the next 3 years, during your SHARE visits.

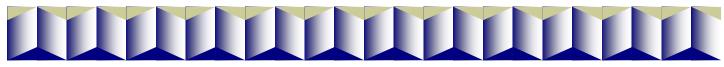
## What Are The Benefits Of Participating?

The study will not directly benefit you but may help researchers better understand risk factors for oral HPV persistence, which could help others in the future

#### Will I Get The HPV Test Results?

You will not receive most of these experimental research test results. These tests are not approved for clinical use and there is no treatment for HPV when detected.

Repeated detection of oral HPV type 16 may mean that you are at higher risk for HPV-associated oral cancer. So, you WILL be told if you have a persistent infection with oral HPV type 16, provided you say you DO want to know this information (in your consent form when you enroll).



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Other new testing will be offered at future visits; we are planning for lung testing at visit 67 (see article in this newsletter) and echocardiograms for visit 68. This testing provides valuable clinical data for the institutes and researchers, and also clinical test results that may be useful for you and your health care providers. We are always glad when we can do studies that benefit the health of our participants. The current thinking is that NHLBI will assume the leading role in the funding of SHARE after 2019, with contributions from other NIH institutes. The level of funding that will be provided, and the specific research and testing agendas of these institutes, are not known at this time.

The continuation of SHARE and the MACS is a testament to the value of these studies and of the contribution you are making to U.S. and world health whether you are HIV-positive or HIV-negative. I cannot thank you enough for this! It is also a testament to a lot of time and effort by SHARE and MACS participants, our advocates at NIH, outside researchers, and members of the community to alert our congressional representatives and NIH staff to the need to continue the work that we are all doing together. None of this is easy. But it is your loyalty to the study that makes it all possible.

My best wishes for a happy and healthy 2017!

Joe

Joseph B. Margolick, MD, PhD Principal Investigator (410) 955-1436, jmargol1@jhu.edu

## We are Looking for You at SHARE!!

Has it been more than six months since your last visit? If so, please contact Lee Savoy at (410) 955-7090 or toll-free at 1 (866) 392-8991 to schedule your next SHARE visit. Keep in mind that distance is not a problem because we can do the interview on the phone at your convenience.

Remember, it is never too late to come back to SHARE. We're looking forward to hearing from you.



### We Need You!

Our Community Advisory Board (CAB) meets the third Thursday of every month (except the summer) from 6:00pm to 8:00pm. The CAB helps SHARE design and carry out studies the way they should be done. Meetings are open to all study participants. A light dinner is served. If you are a CAB member and have missed some meetings, please feel free to come to a meeting as your schedule permits. If you have never attended a meeting, please feel free to join us.

If you want to attend a meeting, please call Jacquett Johnson at (410) 955-7090 or toll free at 1 (866) 392-8991, or email jjohns20@jhu.edu.

You are cordially invited to attend the

# SHARE Research Forum

Thursday, January 26th from 7:00pm to 9:00pm Johns Hopkins School of Public Health, Room E2030 615 N. Wolfe Street, Baltimore, MD

#### \* \* \*Talks will include\* \* \*

	Welcome from the Principal InvestigatorJoseph B. Margolick, MD, PhD
>	PrEP and New Developments in HIV Therapy
>	PrEP in the MACS StudyChristopher Cannon, MPH
>	Preliminary Data from the Healthy Aging StudyMichael Plankey, MD
>	Frailty, Exercise, and Aging Joseph B. Margolick, MD, PhD
>	Present and Future of SHARE and the MACSJoseph B. Margolick, MD, PhD

#### A light dinner will be served at 6:30pm

For more information and to RSVP, please contact Robin Lincoln at 410- 955-7090, or rlincol1@jhu.edu by

Thursday, January 12, 2017.

\* \* \* \*

Free transportation from DC to Baltimore will be provided by bus. If you would like to ride with us, please let us know when you RSVP so that we can make travel arrangements. **Space is limited!** 

We look forward to seeing you!