

## *Letter from the Principal Investigator*



Joseph B. Margolick, MD, PhD

*As* we finish up on 2014, we appreciate that it has been a year of progress and change at SHARE. In April we began our most recent renewal of funding from NIH, which will run until March, 2019. We have had open recruitment and have welcomed new participants, who will help us compare the effects and effectiveness of newer anti-

HIV treatments to those of the older treatments. (Recruitment is still open, as described elsewhere in this newsletter.) We also said thank you and farewell to two long-term staff who have left or retired from SHARE, Dave Baressi and Becky Godfrey, after many years of significant and well-appreciated contributions to SHARE.

SHARE and the other sites in the Multicenter AIDS Cohort Study (MACS) continue to help us understand the long-term effects of HIV infection and antiretroviral therapy on people's health. As you have heard me say before, we are one of the few studies that can compare what happens over time in people living with HIV to what happens in similar HIV-negative people. This has allowed us to make important contributions to the understanding and

treatment of many health conditions, including those affecting the heart, kidneys, nervous system, endocrine system, liver, and other areas of health. In addition, we continue to study why some people control HIV infection better than others, and whether immune or other mechanisms are responsible for this. In all of these studies, the specimens you have provided over the years are vital for our analyses and have been used extensively by dozens of researchers.

Another area of study which continues to become more and more important is that of growing older itself. How people age is something everyone is interested in. SHARE and our colleagues and participants at other sites in MACS are grappling with the complex and difficult question of whether aging is different in people with HIV than in people who don't have HIV. This is a very important question but one that it may take many more years to understand better. It will be particularly valuable to keep tabs on your health as time goes on, so we would very much appreciate it if we could stay in touch with you even if you are not able to come to the SHARE clinics in Baltimore and Washington, DC for your in-person visits.

Continued on page 7

### Inside this issue:

New Studies	2-3
Study Updates	4
News from Whitman-Walker Health	5
SHARE is Recruiting	6
Community Advisory Board Members Needed	7

## Save the Date!

The SHARE Research Forum is scheduled for **Thursday, January 22, 2015** from 7:00pm to 9:00pm at the Thurgood Marshall Center in Washington, DC. SHARE will provide free transportation from Baltimore to Washington, DC before the Forum, and back to Baltimore afterward.

Watch your mail to find out the speakers and the topics.

## New Studies

	<b>MACS Heart Health Study 3</b>	<b>MACS GUT Microbiome-Heart Study</b>	<b>Subclinical Myocardial Abnormalities in MACS/ALIVE/WIHS by Cardiac MRI (SMAsh-CMR)</b>	<b>SHARE Energy Expenditure Study (SEES)</b>
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 persons 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. Final eligibility will be determined later.	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 — 110 from SHARE, 40-60 years of age	200 men (100 HIV+; 100 HIV-), 40 years of age or older, 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, Cardiac Magnetic Resonance Imaging (MRI) with contrast dye, electrocardiogram	DEXA scan, resting energy expenditure assessment (breath analysis), walking energy expenditure assessment (breath analysis), and a physical activity assessment
SHARE Study Coordinators	Mr. Lance Ambrose (410) 955-7090	Mr. Lee Savoy (443) 287-3769	Mr. Lance Ambrose (410) 955-5318	Ms. Robin Lincoln and Mr. Phillip Seaman, (410) 955-7090
SHARE Investigators	Principal Investigator Dr. Wendy Post	Principal Investigators: Drs. Wendy Post and Cynthia Sears Co-Investigator: Joseph Margolick	Principal Investigator Dr. Wendy Post	Principal Investigator Dr. Jennifer Schrack

## New Studies

### SHARE GUT Microbiome-Heart Study

Trillions of bacteria (also called 'bugs' or the microbiome) live in our colons and are now believed to be essential to our health. In health, for example, these bacteria help us digest our food and absorb the nutrients we need to be healthy. However, some of these bacteria are also now thought to contribute to disease including diseases of the gut, obesity, diabetes, hypertension and heart disease (atherosclerosis) among others.

This exciting, new SHARE study aims to determine if we can identify the bacteria in the gut that make products we absorb into our blood that we now know contribute to heart disease. In particular, we aim to understand if changes in our gut bacteria are one of the reasons why HIV-infected men have an increased risk of heart disease. We will enroll both HIV positive and HIV negative men for this study.

### *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 or Lisette Johnson-Hill at (410) 955-7090, or [jmargol1@jhu.edu](mailto:jmargol1@jhu.edu), or [ljohnso6@jhu.edu](mailto:ljohnso6@jhu.edu).



American  
Ginseng

## Volunteers Needed

This is not a SHARE study but is an opportunity for SHARE participants to volunteer for a research study.

### ARE YOU FATIGUED (TIRED)?

If you are HIV-infected you may qualify for a research study evaluating the dietary supplement American ginseng for the treatment of fatigue.

This outpatient study lasts up to 6 weeks and requires you to take study medications for 4 weeks and report for several outpatient visits. The study pays up to \$240 for completion.

Call (410) 502-0033 for more information.  
Principal Investigator: Adriana Andrade, MD  
Protocol NA\_00071671

## Study Updates

### **Effect of HIV Infection and its Treatment on Renal Function in the Multi-center AIDS Cohort Study (MACS) – *The Second Time Around***

The purpose of the kidney study is to investigate whether HIV or HIV treatments are associated with Chronic Kidney Disease (CKD) – when the kidneys have trouble removing waste products from the blood.

We began the kidney study in 2009 and, at that time, a total of 184 men were enrolled. In order to observe changes in kidney function over time, the original 184 men were invited back to complete the study again. To date, 142 men or 77% have completed the second round of this study. Thanks to all who have participated in this study.

If you participated in the first round of the study and have not yet completed the second round, please call the Study Coordinator, Mr. Lee Savoy, at (443) 287-3769.

---

### **MACS Bone Strength Study (BOSS)**

The purpose of the BOSS study is to understand whether older HIV-positive men have a higher risk of fracture (broken bones) than HIV-negative men of similar ages. So far, 150 men have joined the study, out of the goal of 180. Participants in the BOSS study are encouraged to continue reporting their falls to Ms. Robin Lincoln, Study Coordinator, (410) 955-7090.

### **MACS Anal Health Study**

The purpose of this study is to learn more about anal cancer and the human papilloma virus (HPV) that can cause it. Anal cancer is an abnormal growth of cells that starts in the anal area and can spread (metastasize) to other parts of the body. Enrollment for this study began in 2010, and ended in 2011 with 359 men enrolled. Enrollment is now closed except for our new recruits. SHARE staff will follow up directly with new recruits.

Reminder: If you had an abnormal anal pap result, and want to have a High Resolution Anoscopy (HRA) for further diagnosis, please contact us. We will be happy to provide you with a referral.

Thanks for your continued support and participation in this study!

---

### **Prevalence, Persistence, and Risk Factors for Oral Human Papillomavirus (HPV) Infection (POPS Study)**

This study is being done to learn more about the oral human papilloma virus (HPV) infection. HPV is a sexually transmitted virus that can cause anal and cervical cancer and has been recently shown to cause some oral (tonsillar) cancers. This study began in 2009; the study goal is 180 men in Baltimore and 38 in DC. At the end of visit 61 (9/30/2014), 193 men (89%) had completed a POPS study visit.

## News from Whitman-Walker Health

Since I spoke at the SHARE Forum in January 2014, there have been two major clinical updates in HIV treatment and prevention.

First, the Food and Drug Administration approved a new single tablet regimen called Triumeq in August 2014. The new medication contains three drugs – the two drugs in Epzicom, plus the new drug Tivicay – and is a single tablet that is taken just once daily. The development of a new single tablet regimen with Tivicay is an important advancement in HIV treatment. Studies found very few side effects in groups of patients who took Tivicay in blinded trials. Researchers also found that the drug has a stellar resistance profile which means it's an effective therapy for the majority of people with HIV.



Richard Elion, MD

Second, there is a new drug in development that could have significant implications for both HIV treatment and prevention. The medication, called Cabotegravir, is a long-acting injectable integrase inhibitor. The drug remains active in humans for more than 90 days, which means that it could be used as an injection people with HIV might get just four times a year, in combination with other HIV treatments. Injectable cabotegravir is also being studied as a new form of Pre-Exposure Prophylaxis (PrEP). In studies, individuals at risk for getting HIV receive the injection every 90 days to see how well it prevents new infections. Early findings from these studies should be available in 2015.

As the SHARE site Principal Investigator for Whitman-Walker Health, I'd like to thank you for all the time and effort you generously give to SHARE. I have directed more than 20 studies since I've worked at Whitman-Walker and have found that study participants' dedication and passion for research are what make advancements in science via clinical research possible.

Look forward to seeing you at the next SHARE Forum on January 22, 2015.

Sincerely,

*Richard Elion*

### Updates from Whitman-Walker Health

2014 has been an exciting year for the SHARE study at Whitman-Walker Health! We began the year with a goal of recruiting 40 new study participants and are very excited to report that we've recruited 56 as November 2014. The "new recruits" join an already enthusiastic cohort of local men who help make SHARE such a wonderful study. Many of the new participants learned about SHARE through their participation in medical care or other studies at WWH. It's been terrific to offer SHARE as yet another way they can be a part of the Whitman-Walker community.

The longstanding participants have done a lot to make 2014 a great year as well. Engagement in SHARE has always been superb and this year was no exception. Even with a brutal winter, 98% of participants completed their semi-annual SHARE visits.

If you have any questions about SHARE at Whitman-Walker, please contact the study coordinators: Ms. Brittney Cavaliere and Ms. Julia Schwartz at 202-745-6137.

**Please help us to spread the word.**  
**SHARE is recruiting now through the end of March 2015!**

The SHARE study is recruiting new study participants. SHARE is part of the longest-running and largest HIV research study in the U.S. This is a unique opportunity to contribute to the knowledge of HIV disease and HIV therapy over a lifetime. SHARE is **NOT** a treatment study and does **NOT** involve taking experimental medicines. You will continue to receive your medical care from your own medical care provider.

**WHO'S ELIGIBLE:**

- Men who are HIV-positive, do not have AIDS, and are not taking HIV medicines
- Men who are HIV-positive, do not have AIDS, and started taking HIV medicines (highly active antiretroviral therapy) on or after January 1, 2011
- Men who are HIV-negative (will be enrolled as needed to be matched to HIV-positive men)
- Must be between 18-60 years of age

**WHAT'S INVOLVED:**

- Screening visit – an initial screening visit about 30-45 minutes long with \$20 reimbursement for time and effort
- Enrollment visit – a full study visit, lasting about 3-4 hours long with \$30 reimbursement. Additional reimbursement depends on participation in other substudies
- Three-month visit – a follow-up visit about 1-2 hours long approximately three months after the enrollment/baseline visit with \$30 reimbursement for time and effort

**After the above visits:**

- 2 study visits per year – each visit lasts from 2-3 hours with \$30 reimbursement for each visit
- Private interview
- Free lab testing (viral load, T-cells and other infections like hepatitis)
- Free physical examination
- \$30 reimbursement for time and effort for enrollment and study visits

**WHY JOIN?:**

- Help researchers better understand HIV infection and AIDS, including the long-term effects of HIV medicines
- Free and confidential laboratory testing
- Free physical exams and health referrals
- Flexible scheduling, including evenings and weekends in Baltimore or DC
- A friendly, supportive environment with light refreshments
- Join in the fight against HIV/AIDS

**To volunteer or for more information, please contact the SHARE study:**  
(410) 955-7090 or toll free 1 (866) 392-8991



**We have been looking all over for you!**



415 N. Washington Street  
Baltimore, MD 21231

Phone: (410) 955-7090  
Toll free: 1 (866) 392-8991  
Fax: (410) 955-3778

Did you know that we can make **special** arrangements for you to complete your SHARE visit, even if you can't come to the SHARE clinic?

Please call Lee at (410) 955-7090 or toll-free at 1 (866) 392-8991.

Remember, it is never too late to come back to SHARE.

### **Community Advisory Board Volunteers are Needed!**

Our Community Advisory Board serves an important role in the SHARE study. CAB members are usually the first to hear about new studies and offer input about the study design, study procedures, and the way questions are worded.

We are always looking for people to serve on the CAB. The meetings are held the third Thursday of each month, and a light dinner is provided. Come out and meet the Chair and members of our Community Advisory Board and the study Principal Investigator. The meetings are always open. Please give us a call in advance, if possible, so that we can make sure that we have enough food for you. If you want to attend a meeting, please call us at (410) 955-7090, toll free at 1 (866) 392-8991.

**Everyone is welcome!**

### **Letter from the Principal Investigator** (continued from page 1)

As I mentioned, we have been renewed until 2019. That is a testament to the enormous contributions SHARE, MACS, and all of you have made to medical research and to improving people's health everywhere. Unfortunately, the funding environment at NIH has become very tight and we have had, and will have, to adjust to this. In recent years, our actual level of funding has gone down, not up, and we expect this trend to continue. Therefore, we will be looking for new ways to use our budget more efficiently while continuing to address vital research questions and provide you valuable health information. Your thoughts and suggestions on this are very welcome!

All of us at SHARE thank you once again for all the contributions you have made to the health of people everywhere, with and without HIV. We all wish you and your loved ones a happy and healthy holiday season and new year for 2015!

*Joe*

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