INFORMED CONSENT DOCUMENT

Participant’s Name: ____________________________

Project Title: Chronic Co-Morbid Conditions in HIV+ U.S. Adults on Highly-Active Anti-Retroviral Therapy (HAART)

Principal Investigator: Beau Ances MD, PhD

Research Team Contact: Elizabeth Westerhaus MA, Research Patient Coordinator
314/747-1125

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research participant. By signing this form you are agreeing to participate in this study.

• If you have any questions about anything in this form, you should ask the research team for more information.
• You may also wish to talk to your family or friends about your participation in this study.
• Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?
This is a research study. We invite you to participate in this research study because you are a person over 18 years of age who may or may not have HIV infection.

The purpose of this research study is to study:
1. 1. the effect of HIV on cognitive ability/brain functioning,
2. 2. if the brains of people with HIV age faster/have different functioning than the brains of individuals without HIV, and
3. 3. the effect of HAART (highly-active anti-retroviral therapy) on brain functioning.

WHAT WILL HAPPEN DURING THIS STUDY?
If you have HIV infection, to be eligible for the study:
• ☐ you must have been infected for at least 1 year before enrollment

If you do not have HIV infection, you must have had a negative test within the past 3 months. If you do not know your HIV status and wish to participate in the study, you will be asked to have a Rapid HIV test, which is an oral swab of your mouth.

For all participants, to determine your eligibility, you will have a screening evaluation, which includes:
1. Urine pregnancy test (females only, if no proof of tubal ligation, sterilization, etc.)

2. Oral swab HIV test (HIV negative individuals only). It will take about 20 minutes to get your results.

3. A urine drug screening test for cocaine, amphetamines, methamphetamine, barbituates, benzodiazepeines, marijuana, opiates, PCP, methadone, and tricyclic antidepressants.

4. The Neuroimaging Screening Form, which asks questions about your feelings about being inside a closed space like the MRI scanner, questions about history of head injuries, and questions about any metal that subjects may have implanted in your body or any metal piercings that cannot be removed. This takes approximately 5 minutes to complete. We will also ask about any history of STD’s (sexually transmitted diseases) that you may have.

5. A Locator Form with your basic contact information, as well as additional names of people who might also be able to contact you should you be lost to follow up.

6. You will also be asked to sign a Release of Information form so we can obtain your medical records, including but not limited to medical, hospitalization, HIV, substance use/abuse/dependence and mental health records from your doctors, results from prior blood, diagnostic, imaging and laboratory tests and other information obtained from interviews or questionnaires related to your medical care. We may also review the records of any Washington University research study in which you participate. This will allow us to better determine your eligibility, insure and improve your safety, and decrease your burden if the results of tests done in one research study could be used as data for another instead of asking you to unnecessarily repeat a procedure. We will also review your medical records to verify your history of STD’s, as well as labs for and history of cardiovascular risk such as thyroid and liver function, creatinine, c-reactive protein, complete blood counts studies, total fasting cholesterol with LDL/HDL and triglycerides, fasting glucose, and glycosylated hemoglobin, STD history, AST, ALT, fibrinogen-4, GFR, platelets, HCV, IL-6, d-dimer, hsCRP, etc.

If, on the basis of these tests and at the PI’s discretion, you are found to be eligible for the study, you will be asked to complete the following study procedures. When you come for these evaluations, we ask that you refrain from eating or drinking anything besides water for approximately 8 hours prior to the scan, do not have any caffeine for approximately 5 hours, and do not smoke or chew tobacco for approximately one hour.

1. Neuropsychological Tests -- These are exercises that are related to memory, how fast you do things with your hands, and how you pay attention to tasks. There are a number of different tasks; some are timed and some are not. These will take approximately 1 hour to complete.

2. You will also be asked to complete some other questionnaires about your mood, ability to care for yourself, drug and alcohol use, etc. These questions will take approximately 1 hour to complete.
You may skip any questions that make you feel uncomfortable. If, on the mood questionnaire, you indicate that you are experiencing symptoms consistent with depression, we will refer you to someone with whom you can discuss these feelings.

3. MRI -- The MRI scanner is a powerful magnet that uses simple radio waves to take pictures of your brain. There is no pain associated with this procedure. You will be positioned on your back on the scanner bed and made to feel as comfortable as possible. The scanner bed will be moved inside a large tube so that your head and your chest are inside, but you will be able to see out into the room by your feet. During the scan, you will hear loud, rhythmic knocking sounds. Your ears will be covered to keep the noise at a minimum. There is a speaker and a microphone in the scanner so that you can talk to the MRI technician if there is something you need. Once the scan starts, you will need to lie still since moving around will interfere with taking pictures of your brain. You will be able to end the scan at any time if you feel uncomfortable. You may be asked to do a task while in the scanner. The MRI will take approximately 1 hour to complete.

4. Neuromedical examination -- A doctor who is a specialist in nerve conditions (a neurologist) will examine the nerves in your face. The doctor will test your reaction to touch and will test the reflexes in your arms and legs. This will take approximately 10 minutes.

Future Use of Your Data
In the future, we may look at your records (both research and medical records) of imaging and laboratory data that you have had or may have done outside of this study and possibly include information from these records in the data analysis for this study. This would provide our researchers with additional ways to compare the assessments done in this current study with those you may have had in the past or choose to have in the future, either through participating in another research study or just as part of your regular clinical care.

Additionally, Dr. Ances and his colleagues doing approved research studies, both at WUSM and outside of the University, may use your data now and in the future to answer questions about HIV/AIDS, memory, thinking, aging, various neurodegenerative disorders (i.e., Alzheimer’s Disease, HIV-Associated Neurodegenerative Disease, Multiple Sclerosis, other types of dementia, etc.), and other health concerns. This means that the data we collect from your participation in this study may also be analyzed alone or with data gathered in other, separate studies. If we share any of your data with other investigators, the information will be sent by coded ID#.

HOW MANY PEOPLE WILL PARTICIPATE?
Approximately 360 people will take part in this study conducted by investigators at Washington University.

HOW LONG WILL I BE IN THIS STUDY?
If you agree to take part in this study, your involvement will last for approximately 6 hours (screening visit, lasting approximately 2.5 hours, plus MRI/neuropsych testing visit, lasting approximately 3 hours).
Depending on scheduling availability and your preference, these tests may be scheduled all on one day or split into 2 visits.

Approximately two years after your first scan you will be asked to come back and have repeat neuropsychological testing as well as neuroimaging. The tests that you will perform will be similar to those that you performed at the original session. The scanning will also be similar.

**WHAT ARE THE RISKS OF THIS STUDY?**
You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

**RISK OF QUESTIONNAIRES**
**Likely:** None

**Less Likely:**
- You may feel embarrassed or uncomfortable answering questions about your sexual activity and substance use.
- You may experience fatigue or embarrassment from the exercises of memory, movement, and attention. You may discuss any question that concerns you with the coordinator, and you may choose not to answer any question that makes you feel uncomfortable.

**Rare:** None

**RISKS of MRI**
Some things may interfere with Magnetic Resonance Imaging (MRI), and some can be potentially dangerous. You should inform the study doctor if you have any of the following:
- Heart problems
- Pacemaker
- Metal implanted under your skin, such as an insulin pump
- Hearing aid or cochlear implant
- Surgical clips or staples
- Any metal prosthesis. A prosthesis is an artificial body part, like an artificial leg.
- Shrapnel of bullet
- Tattooed eyeliner
- Metal dental items
- Braces
- Pregnancy
**Likely:**
**Metal in or on the body**
The MRI scanner functions like a magnet and any metals in your body can be pulled off by the machine. If you have metal implants (under the skin) such as a pacemaker or metal pins or rods) you may be at risk when you are close to the machine. To minimize this risk, we will ask you a series of questions about metal exposure over the course of your lifetime from work experiences and medical procedures.

**Claustrophobia (fear of small spaces)**
When you have the MRI you will lie on a small bed and the bed will be inserted inside a large tube. The opening of the tube is narrow, and some people can experience claustrophobia (anxiety or nervousness while inside small spaces) when in the scanner. If you believe that you may experience anxiety or nervousness while inside the scanner you should not participate in this study. If you decide to participate in the study and begin to experience claustrophobia while inside the scanner, we will immediately stop the procedure at your request.

**Body Stiffness**
You may also experience stiffness from lying still for a long time while in the scanner.

**Less Likely:** The scanner produces a loud repeating knocking noise during the scan that some people find bothersome. To lessen the noise, you will be given earplugs.

**Rare:**
- □ Occasionally, some people may experience a short period of dizziness or feel faint after being in the scanner.
- □ There is a rare possibility that a serious abnormality may be discovered by the technician during the MRI picture of your brain. In this event, you will be referred to your primary care physician and/or the WUSM Neurology Clinic for clinical follow up and treatment as appropriate

**RISK OF HIV TESTING**
**Likely:** There are no known likely risks of this testing method.

**Less Likely:** There is a risk of finding out that you are HIV positive when you thought you were HIV negative. This could cause some emotional distress, but the study physicians and/or a clinical psychologist will be available to talk with you should you become upset. We will also provide you with a referral for treatment and case management before you leave.

**Rare:** There are no known rare risks of this testing method.

**WHAT ARE THE BENEFITS OF THIS STUDY?**
You will not receive any direct benefit from this study. However, researchers hope to learn more
about how HIV and aging affects various areas of the brain, which will in turn help doctors decide when to initiate medications and help them evaluate the efficacy of any medications that can help protect the brain from the effects of HIV or aging.

WHAT OTHER OPTIONS ARE THERE?
There are no other options to participation in the study.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?
You will not have any costs for being in this research study.

WILL I BE PAID FOR PARTICIPATING?
You will be paid for being in this research study. You will need to provide your social security number (SSN) in order for us to pay you. You may choose to participate without being paid if you do not wish to provide your social security number (SSN) for this purpose. You may also need to provide your address so that a check can be mailed to you. The check will be requested after your complete the study, but it may take about 2 weeks for you to receive it. If your social security number is obtained for payment purposes only, it will not be retained for research purposes.

The total amount of compensation for being in the study will be $100.00. You will be paid for each group of evaluations that you complete as follows:

<table>
<thead>
<tr>
<th>Visit 1</th>
<th>Screening evaluations</th>
<th>$10.00</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visit 2</td>
<td>MRI, neuromedical examination, questionnaires</td>
<td>90.00</td>
</tr>
</tbody>
</table>

Total compensation $100.00

You will be paid only for the visits that you complete.

WHO IS FUNDING THIS STUDY?
The National Institute of Health (NIH) is funding this research study. This means that Washington University is receiving payments from NIH to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from NIH for conducting this study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?
Washington University investigators and staff will try to reduce, control, and treat any complications from this research. If you feel you are injured because of the study, please contact the investigator (Dr. Beau Ances at 314/747-8423) and/or the Human Research Protection Office at 314/633-7400 or 1/800/438-0445.
Decisions about payment for medical treatment for injuries relating to your participation in research will be made by Washington University and NIH. If you need to seek medical care for a research-related injury, please notify the investigator as soon as possible.

**HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?**

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- Government representatives, (including the Office for Human Research Protections) to complete federal or state responsibilities.
- NIH
- University representatives, to complete University responsibilities
- Washington University’s Institutional Review Board (a committee that reviews and approves research studies)
- Public health agencies to complete public health reporting requirements
- Your primary care physician if a medical condition that needs urgent attention is discovered.

To help protect your confidentiality, we will keep all information in a locked area. The information you give us will be given a code number. A master list linking the code number and your identity will be kept separate from the research data. Only the Principal Investigator and people helping him will be able to see the list, and all staff involved with this project have been thoroughly trained in the protection of research participants. We will protect your information, but there is a chance somebody might see it.

If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

Some of the individual results from tests to be performed during this research study might be of interest to you or your primary care physician. At your request, the researchers will share the medical information gained from this study with you and your referring and/or primary care doctors. If we discover significant abnormal test results or an urgent medical condition that requires treatment, we will notify your primary care physician for your health and safety even if you don’t request that we do.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.
To further protect your privacy, the researchers have obtained a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). This Certificate may prevent the researcher from being forced (for example by court subpoena) to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceeding. However, a Certificate of Confidentiality does not prohibit the researcher from disclosing information about you or your involvement in this research that you have agreed to disclose or make available. For example, if you or your legally authorized representative request in writing that information about you or your participation in the research be released to an insurance company, the researcher may not use the Certificate of Confidentiality to withhold this information. This means that you and your family should actively protect your own privacy. Finally, the researcher is not prevented from taking steps, including reporting to appropriate authorities, to prevent child abuse or serious harm to yourself or others.

**Are there additional protections for my health information?**

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, “How will you keep my information confidential?”.

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University’s Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

May we contact you for future undetermined studies conducted by Dr. Ances or his colleagues?

_____Yes  _____No

If yes, we will need to look at your Protected Health Information (PHI) to check for study eligibility.

**If you decide not to sign this form, it will not affect**

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.
If you sign this form:

- You authorize the use of your PHI for this research.
- Your signature and this form will not expire as long as you wish to participate.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
- To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at http://hrpo.wustl.edu (or use the direct link: http://hrpohome.wustl.edu/participants/WithdrawalTemplate.rtf) or you may request that the Investigator send you a copy of the letter.
  - If you revoke your authorization:
    - The research team may only use and share information already collected for the study.
    - Your information may still be used and shared if necessary for safety reasons.
    - You will not be allowed to continue to participate in the study.

IS BEING IN THIS STUDY VOLUNTARY?
Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. If you decide not to be in this study, or if you stop participating at any time, you won’t be penalized or lose any benefits for which you otherwise qualify.

What if I decide to withdraw from the study?
You may withdraw by telling the study team you are no longer interested in participating in the study or you may send in a withdrawal letter. A sample withdrawal letter can be found at http://hrpo.wustl.edu under Information for Research Participants.

There will be no adverse consequences or changes to your insurance or health care if you choose to no longer participate in the study.

Will I receive new information about the study while participating?
If we obtain any new information during this study that might affect your willingness to continue participating in the study, we’ll promptly provide you with that information.

Can someone else end my participation in this study?
Under certain circumstances, the researchers might decide to end your participation in this research study earlier than planned. This might happen because if you have certain medical conditions like seizures, use of illegal drugs, or pregnancy or because in our judgment it would not be safe for you to continue, or because the funding for the research study has ended.
WHAT IF I HAVE QUESTIONS?
We encourage you to ask questions. If you have any questions about the research study itself, please contact: Elizabeth Westerhaus at 314/747-1125 or Dr. Beau Ances at 314/747-8423. If you feel that you have been harmed in any way by your participation in this study, please contact Dr. Beau Ances at 314/747-8423.

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office, 660 South Euclid Avenue, Campus Box 8089, St. Louis, MO 63110, (314) 633-7400, or 1-(800)-438-0445 or email hrpo@wusm.wustl.edu. General information about being a research participant can be found by clicking “Participants” on the Human Research Protection Office web site, http://hrpohome.wustl.edu. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed and dated copy of this form.

Do not sign this form if today’s date is after EXPIRATION DATE: 12/18/14.

_________________________________________ _______________________________
(Signature of Participant)     (Date)

____________________________________________
(Participant's name – printed)

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant’s legally authorized representative. The participant has indicated that he or she understands the risks, benefits, and procedures involved with participation in this research study.

__________________________________________ _______________________________
(Signature of Person who Obtained Consent)   (Date)

__________________________________________
(Name of Person who Obtained Consent - printed)