CONSENT FORM

TITLE OF RESEARCH: Executive Function Training to Reduce Cognitive Intra-Individual Variability in Adults with HIV (The EFT Study)

IRB PROTOCOL NO.: FXXXXXXXXXX

INVESTIGATOR: David E. Vance, PhD, MGS

SPONSOR: National Institutes on Aging

SPONSOR PROTOCOL NO.: 1 R21 AG077957-01

General Information	You are being asked to take part in a research study. This research study is voluntary, meaning you do not have to take part in it. The procedures, risks, and benefits are fully described further in the consent form.
Purpose	The purpose of the study is to see if executive functioning training can improve the ability to think in people with HIV-Associated Neurocognitive Disorder (or HAND).
Duration & Visits	This study consists of a 2-hour baseline visit, 20 hours of cognitive training, and a 2-hour posttest visit. All of this will be conducted at our UAB research center (924 19th Street South, Holley-Mears Building).
Overview of Procedures	This study will include being asked questions about your health and taking cognitive tests to see if you have HAND. If you do, you will be invited to do 20 hours of cognitive training (called Executive Function Training or EFT) or to do nothing (if nothing, you are in the control group). After about 12 weeks, we will ask you to come back for a posttest visit where we will again ask questions about your health and you take cognitive tests.
Risks	The most common risks include boredom, being randomized, loss of confidentiality, and being exposed to question about mood or drug use.
Benefits	You may or may not benefit from this study. A potential benefit is that you may be able to think better.
Alternatives	If you do not want to take part in the study, you are not required to be a part of this study.

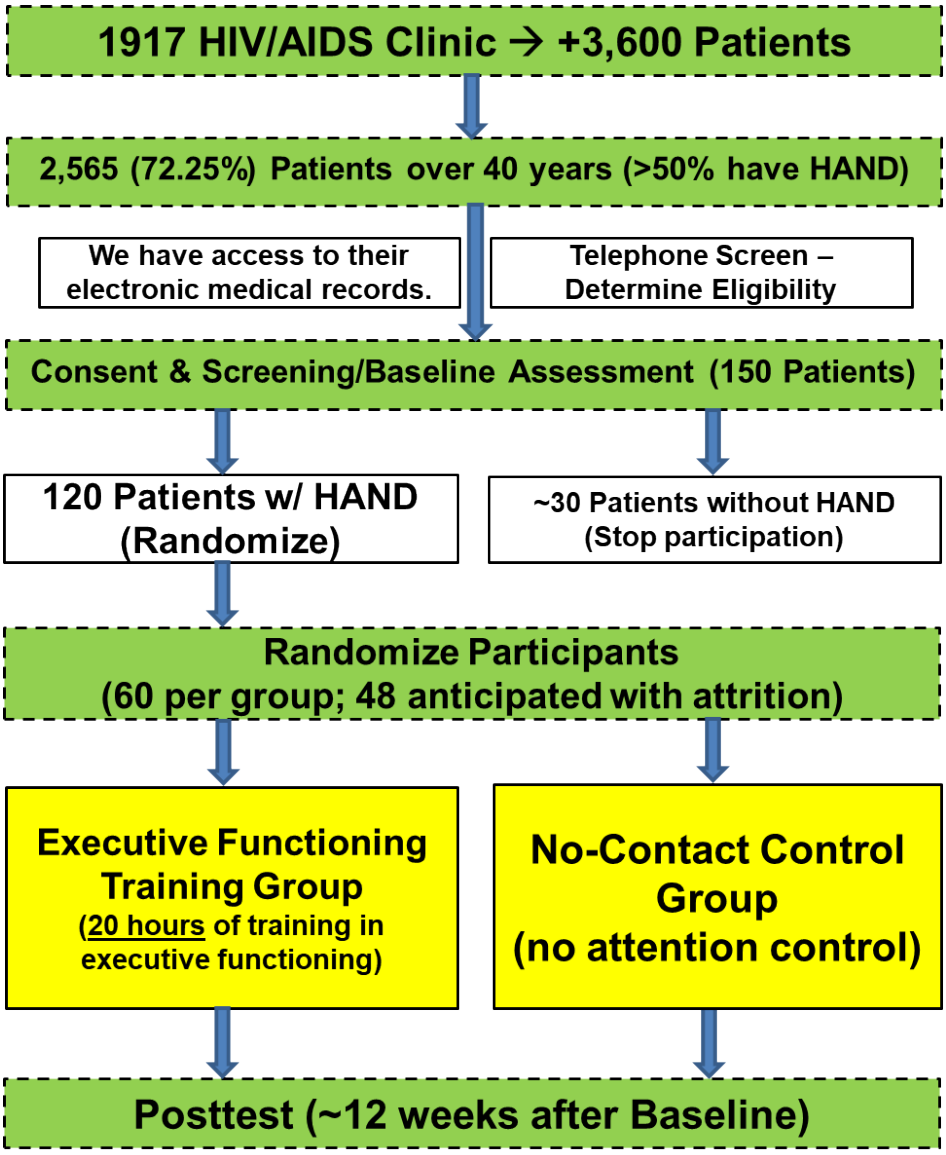
Purpose of the Research

We are asking you to take part in a research study. This research study will examine how engaging certain mental exercises will improve your ability to think. We are using a variety of computerized mental exercises that can be used to improve executive functioning, which is your ability to reason and plan. We will also be examining whether engaging in this type of training will improve cognitive intra-individual variability, which means how much one's thinking fluctuates. Also, we will ask you questions about what you liked and did not like about playing these mental exercises. We will also examine whether this Executive Functioning Training will reduce the prevalence or severity of **H**IV-**A**ssociated **N**eurocognitive **D**isorder (or HAND for short). These mental exercises are commercially available through POSIT SCIENCE, Inc.

This study will initially enroll approximately 150 participants to see if they meet study criteria; only 120 will be enrolled fully into this study and only 60 will receive the mental exercises. All participants will come from UAB.

Explanation of Procedures

See flowchart of the study below and the following description.



Baseline Assessment (First/Initial Visit)

If you enter the study, we will first administer what we call the Baseline Assessment which will take approximately 2 hours. During this assessment, we will ask you to complete several questionnaires about your health, what medicines or drugs (legal or illegal) you take, what your mood is such as being anxious or depressed, and so forth. We are only using this drug information in data analyses to see how it impacts the way people think. With the information you give us, we will also access your medical records at the 1917 UAB Clinic. Based upon the information that is collected, we will determine whether you qualify to continue with the study.

We are looking at your mental functioning in case you are not performing as close to your age and educational level as we would expect; we call this **H**IV-**A**ssociated **N**eurocognitive **D**isorder or **HAND** for short. A little over half of everyone with HIV has HAND to some degree; so this should not be a cause for alarm if you meet these criteria; we simply use this term to categorize how people are mentally functioning. We will send you an information letter describing HAND if you have this condition. If it looks like you may have this condition, this study is designed to see if we can improve the way you think. It will take a few days after the Baseline Assessment for us to determine if you have HAND; at which point, we will give you a call as to whether you can continue with this study or not. Only those who have this condition will be invited to continue with this study.

If you do meet the study criteria, we will then randomized (like the flip of a coin) you to one of two conditions. The two conditions are: 1) a No-Contact Control Group or 2) 20 hours of an Executive Functioning Training Group. Those in the No-Contact Control Group will only do the Baseline Assessment and a Posttest Assessment approximately 12 weeks later.

Mental Exercise Training/Executive Function Training Group

Those randomized to participate in this Individualized-Targeted Cognitive Training Group will be asked to come to our center (924 19th Street South, UAB – Holley-Mears Building) for 1 to 2 hour(s) appointments, typically spread out over approximately 10-12 weeks. If you are in this group, depending on your availability and for your convenience, you may complete up to 2 hours of training at a time to cut down on your travel time. Also, if you like, you can schedule these appointments several times during the week to complete the training as early as possible, depending on your availability. During these appointments, study staff will direct you as to how you should engage in the mental exercises on the computer. In other words, they will tell you which computer games to play to strengthen your executive functioning ability. Study staff will be available to answer any questions you have about the mental exercises and will schedule your next appointment(s). Once you have completed 20 hours of mental exercises, study staff will schedule your Posttest Assessment appointment.

Posttest Assessment

This Posttest Assessment will be just like the Baseline Assessment. During this assessment, we will ask you to complete several questionnaires about your health, what medicines or drugs (legal or illegal) you take, what your mood is such as being depressed, and so forth. In addition, we will give you several interactive tests that measure how well you think. As before with the Baseline Assessment, this Posttest Assessment should take approximately 2 hours.

Risks and Discomforts

Randomization

You will be assigned to a group by chance, which may prove to be less effective or to have more side effects than the other study group(s) or alternatives. Likewise, the mental exercises you are randomized to may be more boring or fatiguing to you.

Boredom/Fatigue

It is possible that you may become bored or fatigued when doing the mental exercises. To alleviate this, you may take breaks as needed during your training sessions.

Embarrassment
You may become embarrassed because we are asking you to provide some sensitive information about your mood or substance use. Also, some people find it difficult to perform the mental tests we give which can cause embarrassment; however, these tests are designed to be very challenging so we can see what you are able to do. For these reasons, that is why we conduct all the assessments with you in privacy and keep all of your information confidential.

Confidentiality
There is always a risk of loss of confidentiality with all studies. However, we minimize this risk by first conducting all the assessments privately in a room devoted to collecting such information. Second, we minimize this risk by not having your name on any of the data collection forms used in this study. Third, the data will be put in an electronic database that will not have any information in it that can identify you. Information that can identify you (such as this consent form, contact information, W-9, *et cetera*) will not be stored with these data collection forms. Fourth, the data collected in this study will be presented and published in aggregate (groups) and it will not be possible to identify anyone specifically from this. Finally, only Dr. Vance and the Program Manager will have the key to link your participant identification number on the data collection forms with your identity; this key will be encrypted on our password protected computers in our locked offices within the UAB School of Nursing.

Substance Use
We will be gathering self-reported information on your substance use (e.g., alcohol, cocaine, *et cetera*) using a questionnaire. As mentioned above, we will keep this information confidential as specified above. If you do report the use of substances or alcohol, that will NOT interfere with your participation in this study; we just need to know this information for analyzing our results.

Benefits

You may or may not benefit directly from taking part in this study. However, you may improve your ability to think more clearly or quickly as a result of engaging in these mental exercises. Also, improvements in such thinking may also improve your ability to do everyday activities as well as improve your quality of life over time. But we are not certain of these outcomes; that is why this study is being conducted.

Alternatives

The alternative to participating in this research study is not to participate.

Confidentiality

Information obtained about you for this study will be kept confidential to the extent allowed by law. However, research information that identifies you may be shared with the UAB

Institutional Review Board (IRB) and others who are responsible for ensuring compliance with laws and regulations related to research, including people on behalf of the National Institute on Aging/National Institutes of Health and the Office for Human Research Protections (OHRP). The information from the research may be published for scientific purposes; however, your identity will not be given out.

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.

Information obtained during the course of the study which, in the opinion of the investigator(s), suggests that you may be at significant risk of harm to yourself or others will be reportable to a third party in the interest of protecting the rights and welfare of those at potential risk.

Voluntary Participation and Withdrawal

Whether or not you take part in this study is your choice. There will be no penalty if you decide not to be in the study. If you decide not to be in the study, you will not lose any benefits you are otherwise owed. You are free to withdraw from this research study at any time. Your choice to leave the study will not affect your relationship with this institution. If you wish to leave the study, you simply have to call us or tell study staff; we will compensate you for the time that you have spent with the study.

You may be removed from the study without your consent if the sponsor ends the study, if the study principal investigator decides it is not in the best interest of your health, or if you are not following the study rules.

If you are a UAB student or employee, taking part in this research is not a part of your UAB class work or duties. You can refuse to enroll, or withdraw after enrolling at any time before the study is over, with no effect on your class standing, grades, or job at UAB. You will not be offered or receive any special consideration if you take part in this research.

Cost of Participation

There will be no cost to you for taking part in this study. All assessments and mental exercises related to this study will be provided to you at no cost during the 2-year study period.

Payment for Participation in Research

Baseline Assessment

You will be paid $50 for completing the Baseline Assessment. Payment will be made with greenphire clinic cards which we will give you. These cards are like credit cards and can be used anywhere.

Mental Exercise Training/Executive Function Training Group

You will be paid $15 for each hour of mental exercise you do at our center. One payment will be made after the first 10 hours of training completed and then another payment will be made after the second 10 hours of training completed; again, these payments will be placed on your greenphire clinic cards. If you withdraw from the study, you will be paid for the hours that you completed; this will take place approximately 2 week from the time we are notified that you are withdrawing from the study.

Posttest Assessment
You will be paid $75 for completing the Posttest Assessment. Payment will be made with greenphire clinic cards which we will give you.

Altogether
For those in the No-Contact Control Group, the maximum you will be paid is $125.
For those in the 20-hours of Executive Function Training Group, the maximum you will be paid is $425.

Payment for Research-Related Injuries

UAB and the National Institutes of Health have not provided for any payment if you are harmed as a result of taking part in this study. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge.

Significant New Findings

You will be told by Dr. Vance or the study staff if new information becomes available that might affect your choice to stay in the study.

Questions

If you have any questions, concerns, or complaints about the research or a research-related injury including available treatments, you may contact Dr. David Vance. He will be glad to answer any of your questions. Dr. Vance's number is 205-934-7589.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday. You may also call this number in the event the research staff cannot be reached or you wish to talk to someone else.

Legal Rights

You are not waiving any of your legal rights by signing this informed consent document.

Signatures

Your signature below indicates that you have read (or been read) the information provided above and agree to participate in this study. You will receive a copy of this signed consent form.

Signature of Participant	Date
Signature of Witness	Date

Reviewed by:

Signature of Principal Investigator Reviewing Consent Document	Date

University of Alabama at Birmingham
AUTHORIZATION FOR USE/DISCLOSURE OF
PROTECTED HEALTH INFORMATION (PHI) FOR RESEARCH

Participant Name: _____
Research Protocol: Executive Function Training to Reduce Cognitive Intra-Individual Variability in Adults with HIV (The EFT Study)

UAB IRB Protocol Number: FXXXXXXX
Principal Investigator: Dr. David E. Vance, PhD, MGS
Sponsor: National Institute on Aging/National Institutes of Health

What is the purpose of this form? You are being asked to sign this form so that UAB may use and release your protected health information for research. Participation in research is voluntary. If you choose to participate in the research, you must sign this form so that your protected health information may be used for the research.

Why do the researchers want my protected health information? The researchers want to use your protected health information as part of the research protocol listed above and as described to you in the informed consent.

What protected health information do the researchers want to use? All medical information, including but not limited to information and/or records of any diagnosis or treatment of disease or condition, which may include sexually transmitted diseases (e.g., HIV, etc.) or communicable diseases, drug/alcohol dependency, etc.; all personal identifiers, including but not limited to your name, social security number, medical record number, date of birth, dates of service, etc.; any past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of whatever kind, including but not limited to drug/alcohol treatment, psychiatric/psychological treatment; financial/billing information, including but not limited to copies of your medical bills, and any other information related to or collected for use in the research protocol, regardless of whether the information was collected for research or non-research (e.g., treatment) purposes.

Who will disclose, use and/or receive my protected health information? All Individuals/entities listed in the informed consent documents, including but not limited to, the physicians, nurses and staff and others performing services related to the research (whether at UAB or elsewhere); other operating units of UAB, HSF, UAB Highlands, Children's of Alabama, Eye Foundation Hospital, and the Jefferson County Department of Health, as necessary for their operations; the IRB and its staff; the sponsor of the research and its employees and agents, including any CRO; and any outside regulatory agencies, such as the Food and Drug Administration, providing oversight or performing other legal and/or regulatory functions for which access to participant information is required.

How will my protected health information be protected once it is given to others? Your protected health information that is given to the study sponsor will remain private to the extent possible, even though the study sponsor is not required to follow the federal privacy laws. However, once your information is given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected.

How long will this Authorization last? Your authorization for the uses and disclosures described in this Authorization does not have an expiration date.

Can I cancel this Authorization? You may cancel this Authorization at any time by notifying the Principal Investigator, in writing, referencing the research protocol and IRB Protocol Number. If you cancel this Authorization, the study doctor and staff will not use any new health information for research. However, researchers may continue to use the protected health information that was provided before you cancelled your authorization.

Can I see my protected health information? You have a right to request to see your protected health information. However, to ensure the scientific integrity of the research, you will not be able to review the research information until after the research protocol has been completed.

Signature of participant: _____ Date: _____