ADULT CONSENT - NON-CLINICAL BIOMEDICAL

A mobile study to characterize HIV-related neurocognitive disorders

Title of this Research Study

A mobile study to characterize HIV-related neurocognitive disorders

Invitation

You are invited to take part in this research study. At the end of this informed consent, you have copies of these two documents, which are meant to help you decide whether or not to take part:

- "What Do I need to Know Before Being in a Research Study?"
- The Rights of Research Subjects

Why are you being asked to be in this research study?

The target population for this study is individuals 19-79 years of age who have tested positive for exposure to HIV. Currently the study is only available to participants who live in the United States and have access to an iOS device, such as an iPhone. Individuals who have not been diagnosed with HIV or express a disability related to using the iPhone will still be allowed to use the application for comparison purposes.

What is the reason for doing this research study?

This study aims to improve the understanding of neurocognitive disorders in HIV-positive patients. The purpose of the study is to measure and describe cognitive performance in adults with HIV compared to those without HIV infection by using a newly developed iPhone-based neuropsychological (NP) screening battery to identify human immunodeficiency virus (HIV)-infected individuals who have NP impairment. The study is expected to last one year.

What will be done during this research study?

The study will consist of neurocognitive tests and surveys to be completed on a week-to-week basis. A dashboard is included that allows you to track your performance over time.

1. Using an iOS device, you will take a series of BrainBaseline cognitive assessments on a weekly basis for the first month, then monthly thereafter. These assessments have been designed to be self-administered. This means you will follow the instructions that appear on the screen. The iPhone tests consist of an evaluation of your thinking skills, including attention/working memory (i.e., holding new information in mind to be able to use it later), learning/memory, decision-making, and speed of responding, and motor functioning. Completing all five assessments each week will take approximately 15 minutes, with an average time of 3 minutes per

assessment.

2. You will be asked to complete surveys about your health, demographics, exercise habits, and leisure activities on your iOS device.Health information will be gathered and recorded via your devices Health app.
3. You will complete a few short surveys to understand general demographic and lifestyle information.
4. As a participant, you will be asked to complete weekly BrainBaseline assessments for the first month, to track cognitive function over the course of the study, then monthly thereafter.
5. We anticipate that the first entry into the app will take from 45 minutes to an hour. Follow up assessments will probably take less than 30 minutes. You will be able to skip questions and sections of the testing.
6. - See more at: https://www.handinhandstudies.org

What are the possible risks of being in this research study?
Possible risks associated with participating in this study include boredom or possible eye strain associated with the testing, and the possible risk of a loss of confidentiality.

What are the possible benefits to you?
You are not expected to get any benefit from being in this research study.

What are the possible benefits to other people?
The knowledge gained may help others in the future.

What are the alternatives to being in this research study?
This study is a broad study made available through iTunes. Instead of being in this research study, you can choose not to participate.

What will being in this research study cost you?
There is no cost to you to be in this research study.

Will you be paid for being in this research study?
You will not be paid to be in this research study.

Who is paying for this research?
This research is being paid for by funds from the Department of Pharmacology and Experimental Neuroscience of the University of Nebraska Medical Center. Digital Artefacts, LLC. provided design and development of the application and infrastructure for the study.

What should you do if you are injured or have a medical problem during this research study?
Your welfare is the main concern of every member of the research team. If you are injured or have a medical problem or some other kind of problem as a direct result of being in this study, you should immediately contact one of the people listed at the end of this consent form.

How will information about you be protected?
All necessary steps will be taken to protect your privacy and the confidentiality of your study data.

Who will have access to information about you?
By signing this consent form, you are allowing the research team to have access to your research data. The research team includes the investigators listed on this consent form and other personnel involved in this specific study at UNMC.

Your research data will be used only for the purpose(s) described in the section "What is the reason for doing this research study?" De-identified data may be shared with other authorized researchers after the completion of the study.

You are also allowing the research team to share your research data, as necessary, with other people or groups listed below:

- The UNMC Institutional Review Board (IRB)
- Institutional officials designated by the UNMC IRB
- Data will be stored in a secure database created and managed by Digital Artefacts, LLC; hosted on servers using Amazon Web Services.
- Federal law requires that your information may be shared with these groups:
    - The HHS Office for Human Research Protections (OHRP)

You are authorizing us to use and disclose your research data for as long as the research study is being conducted.

How will results of the research be made available to you during and after the study is finished?
In most cases, the results of the research can be made available to you when the study is completed , and all the results are analyzed by the investigator or the sponsor of the research. The information from this study may be published in scientific journals or presented at scientific meetings, but your identity will be kept strictly confidential.

If you want the results of the study, contact the Principal Investigator at the phone number given at the end of this form or by writing to the Principal Investigator at the following address:
Howard S Fox, M.D., Ph.D.
985800 Nebraska Medical Center
Omaha, NE 68198
402 559-4820
or by email: hfox@unmc.edu

What will happen if you decide not to be in this research study?
You can decide not to be in this research study. Deciding not to be in this research will not affect your relationship with the investigator or UNMC. You will not lose any benefits to which you are entitled.

What will happen if you decide to stop participating once you start?
You can stop participating in this research (withdraw) at any time by contacting the Principal Investigator or any of the research staff. Deciding to withdraw will otherwise not affect your care or your relationship with the investigator or UNMC. You will not lose any benefits to which you are entitled. Any research data obtained to date may still be used in the research.

Will you be given any important information during the study?
You will be informed promptly if the research team gets any new information during this research study that may affect whether you would want to continue being in the study.

What should you do if you have any questions about the study?
Attached is a copy of "What Do I Need to Know Before Being in a Research Study?" If you have any questions at any time about this study, you should contact the Principal Investigator or any of the study personnel listed on this consent form or any other documents that you have been given.

What are your rights as a research subject?
You have rights as a research subject. These rights have been explained in this consent form and in The Rights of Research Subjects that you have been given. If you have any questions concerning your rights or complaints about the research, you can contact any of the following:

- The investigator or other study personnel
- Institutional Review Board (IRB)
    - Telephone: (402) 559-6463

- Email: IRBORA@unmc.edu
- Mail: UNMC Institutional Review Board, 987830 Nebraska Medical Center, Omaha, NE 68198-7830

- Research Subject Advocate
  - Telephone: (402) 559-6941
  - Email: unmcrsa@unmc.edu

Documentation of informed consent

You are freely making a decision whether to be in this research study. Signing this form, electronically or otherwise, means that:

- You have read and understood this consent form.
- You have had the consent form explained to you.
- You have been given a copy of The Rights of Research Subjects
- You have had your questions answered.
- You have decided to be in the research study.
- If you have any questions during the study, you have been directed to talk to one of the investigators listed below on this consent form.

Signature of Subject _____ Date _____

Authorized Study Personnel

Principal

* Fox, Howard
phone: 402-559-4821
alt #: 402-559-4000
degree: MD PhD

Lead Coordinator

Morsey, Brenda
phone: 402-559-5322
alt #: 402-709-2990
degree: MS

What Do I Need To Know Before Being In A Research Study?

You have been invited to be in a **research study**. Research studies are also called "research surveys", "research questionnaires" or "scientific protocols." **Research** is an organized plan designed to get new knowledge about health, disease, behaviors, attitudes and interactions of, among and between individuals, groups and cultures. The people who are in the research are called **research subjects**. The **investigator** is the person who is running the research study. You will get information from the investigator and the research team, and then you will be asked to give your **consent** to be in the research.

This sheet will help you think of questions to ask the investigator or his/her staff. You should know all these answers before you decide about being in the research.

What is the **purpose** of the research? Why is the investigator doing the research?

What are the **risks** of the research? What bad things could happen?

What are the possible **benefits** of the research? How might this help me?

How is the research different than what will happen if I m not in the research?

Will being in the research **cost** me anything extra?

Do I have to be in this research study? How will it affect my status at the institution if I say **no**?

Can I **stop** being in the research once I ve started? How?

Who will look at my **records**?

How do I reach the investigator if I have more **questions**?

Who do I call if I have questions about being a **research subject**?

Make sure all your questions are answered before you decide whether or not to be in this research.

THE RIGHTS OF RESEARCH SUBJECTS
AS A RESEARCH SUBJECT YOU HAVE THE RIGHT

to be told everything you need to know about the research before you are asked to decide whether or not to take part in the research study. The research will be explained to you in a way that assures you understand enough to decide whether or not to take part.

to freely decide whether or not to take part in the research.

to decide not to be in the research, or to stop participating in the research at any time. This will not affect your medical care or your relationship with the investigator or the Nebraska Medical Center. Your doctor will still take care of you.

to ask questions about the research at any time. The investigator will answer your questions honestly and completely.

to know that your safety and welfare will always come first. The investigator will display the highest possible degree of skill and care throughout this research. Any risks or discomforts will be minimized as much as possible.

to privacy and confidentiality. The investigator will treat information about you carefully, and will respect your privacy.

... to keep all the legal rights you have now. You are not giving up any of your legal rights by taking part in this research study.

to be treated with dignity and respect at all times

The Institutional Review Board is responsible for assuring that your rights and welfare are protected. If you have any questions about your rights, contact the Institutional Review Board at (402) 559-6463.