Aim 1 Adult Beta Test Informed Consent

Title of Research Study: ***Pragmatic Efficacy Trial of mHealth to Improve HIV Outcomes in the DC Cohort***
Investigator: ***Amanda D. Castel, MD, MPH, Department of Epidemiology***

IRB# NCR202829

Key Information:

You are being asked to take part in a research study to understand if having access to a smartphone app can improve regular participation in HIV medical care (also known as retention in care) and maintenance of a viral load below a certain level (also known as viral suppression) among people living with HIV. This page will give you key information to help you decide whether or not you want to participate in this study. More detailed information can be found on the next pages. Ask the research team questions during the consent process, and use the contact information on this form to ask questions later.

WHAT IS THE PURPOSE, PROCEDURES, AND DURATION OF THIS STUDY?

You are being asked to take part in a "beta test" which means you will download and use a specific mobile application for a 1-month period. You will also be asked to attend a session where you will be shown how to use the application and will also complete a brief demographic survey. After one month of using the application, you will participate in a 15-minute interview and smartphone app feedback survey where you will answer questions on a certain topic with 1 or 2 members of the research team.

Testing the mobile application may help the research team identify any unexpected issues with features of the app or other unexpected technical issues. This information will be used to make changes to the smartphone app, plan and create health programs, and to create new ways of improving retention in care and viral suppression among people living with HIV. Your participation in this research will last about 1 month.

WHAT ARE THE REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You will not benefit directly by being in this study. You may be given information on HIV care and treatment.

WHAT ARE THE REASONS YOU MIGHT NOT CHOOSE TO VOLUNTEER FOR THIS STUDY?

The main risk of this study is the loss of your privacy or confidentiality, including someone outside of the research finding out that you participated. Steps will be taken (detailed below) to reduce that risk

DO YOU HAVE TO TAKE PART IN THIS STUDY?

You do not have to take part in this research. It is your choice whether or not you want to take part. You can agree to take part and later change your mind. If you choose not to take part or choose to stop taking part at any time, there will be no punishment to you or loss of benefits that you would otherwise receive.

WHAT IF YOU HAVE QUESTIONS OR CONCERNS?

The person in charge of this study is Amanda Castel, M.D., M.P.H. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study her contact information is: (202) 994-8325.

This research is being overseen by an Institutional Review Board ("IRB"). You may talk to them at 202-994-2715 or via email at ohrirb@gwu.edu if:

- You have questions, concerns, or complaints that are not being answered by the research team or if you wish to talk to someone independent of the research team.
- You have questions about your rights as a research subject.

Detailed Consent Form:

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you are a person living with HIV who is enrolled in the DC Cohort.

Who can I talk to if I have questions?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at 202-994-8325.

This research is being overseen by an Institutional Review Board ("IRB"). You may talk to them at 202-994-2715 or via email at ohrirb@gwu.edu if:

- You have questions, concerns, or complaints that are not being answered by the research team or if you wish to talk to someone independent of the research team.
- You have questions about your rights as a research subject.

Why is this research being done?

This research study is being led by The University of Virginia (UVA) and The George Washington University (GWU). The purpose of this study is to understand if having access to a smartphone app can improve retention in care and viral suppression among persons living with HIV (PLWH). Information collected in this research study will be used to:

- Determine what people living with HIV know about retention in care and viral suppression
- Determine what makes it easy and what makes it difficult to participate in regular HIV medical care and maintain of a viral load below a certain level
- Determine what app features are most relevant for patients
- Inform the adaptation of the app most useful for retention in care
- Guide future research on retention in care and viral suppression

How long will I be in the study?

We expect that you will be in this research study for about 1 month.

How many people will take part in this research study?

We expect about 14 people will take part in this part of the study.

What happens if I agree to be in this research?

If you agree to be in this study, this is what will happen:

1. You will be asked to take part in a beta test which involves downloading a specific mobile application. You must have your own mobile Apple or Android phone. You will

be asked to attend a session to show you how to use the application and complete a brief demographic survey .

2. For a 1-month period, you will have unlimited access to all of the application features. During that time, we will monitor your use of the application (e.g. number of logins, length of time using the application, screens viewed, features used, etc.). We will not have access to other information on your mobile device.

3. After 1 month of using the application, we will ask you to participate in an interview and complete a survey where 1-2 members of the research staff will ask you questions about your experience using the mobile application. The interview will be audio recorded to ensure that your responses are complete and accurate. The audio recording that comes from the interview will be kept for up to three years after the study has ended. After that time, it will be destroyed. The tape will not be directly connected to your name or identifying information.

4. During the interview, we will assign you a pretend name to help protect your confidentiality. Every effort will be made to protect your information however, this cannot be promised and there is the possible risk that someone will find out you participated in the interview. You may refuse to answer any of the questions, and you may take a break at any time during the session. You may stop taking part in this study at any time. The interview will be confidential and whatever is shared during the interview should not be discussed outside of this session.

What other choices do I have besides taking part in the research?

You may choose not to participate in this study.

What happens if I agree to be in research, but later change my mind?

This study is completely VOLUNTARY. If you agree to participate, you are free to quit at any time. You may refuse to participate or you may discontinue your participation at any time without punishment or loss of benefits that you would otherwise receive.

Is there any way being in this study could be bad for me?

The main risk of this study is the loss of your privacy or confidentiality, including someone outside of the research finding out that you participated.

Will being in this study help me in any way?

You will not benefit directly by being in this study. You may be given information on HIV treatment and care. Testing the mobile application may help the research team identify any unexpected issues with features of the app or other unexpected technical issues. This information will be used to make changes to the related mobile application, plan and create health programs, and to create new ways of increasing retention in care and viral suppression among people living with HIV.

Can I be removed from the research without my permission?

The investigator can decide to withdraw you from the study at any time. You could be taken off the study for reasons related solely to you (for example, not following study-related directions from the investigator) or because the entire study is stopped.

What happens to my information collected for the research?

The GWU and UVA research team will take special care to protect the information you provide. Your responses will not be associated with your name. The mobile application that we are testing is called PositiveLinks. The PositiveLinks application has a sign in screen and requires a username and password to open. You will be automatically signed out when you use another app or when the smartphone is locked. Biometric (i.e. fingerprint) authentication is also available. All data transmitted between the PositiveLinks app and servers is encrypted. The servers are kept in a secure environment. Physical access to these servers are prohibited and the data is stored on encrypted hard drives.

During the interview you will only be identified by a pseudonym or pretend name. No one except the study staff at UVA and GWU will have access to the information provided in the interview. Your responses will be grouped with interview responses from other persons being interviewed. Direct quotes from this interview may be used in reports or transcripts. However, no personal identifiers will be used, and the format would include language such as “A participant stated that "XXX". While your responses are not associated with your real name, there is a very slight chance that an unauthorized person may get access to them. We will take a number of steps to help prevent this:

1. The digital recording will be stored in a secured file on a computer. Only specific members of the study staff will have access to this file.
2. Your name or other identifying information will not be included on or associated with any publication of the research.
3. You may refuse to answer any questions at any time for any reason. If you refuse to answer a question or want to end your participation you will not be penalized in any way.

We will do everything we can to keep others from learning about your participation in this study. To further help us protect your privacy, we have obtained a Certificate of Confidentiality from the United States Department of Health and Human Services (DHHS). With this certificate, we cannot be forced (for example by court order or subpoena) to disclose information that may identify you in any federal, state, local, civil, criminal, legislative, administrative, or other proceedings. You should understand that a Certificate of Confidentiality does not prevent you, or a member of your family, from voluntarily releasing information about yourself or your involvement in this study. The researchers however, will not disclose voluntarily, or without your consent, information that would identify you as a participant in this research project, except to prevent serious harm to you or others, as explained below.

If an insurer, medical provider, or other person learns about your participation, and obtains your consent to receive research information, then we may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also

actively protect your own privacy. You should understand that we will in all cases, take the necessary action and report to authorities, any indication of abuse, and to prevent serious harm to yourself, children, or others, for example, as in the case of child abuse or neglect, or harm to yourself or others. Disclosure will be necessary, however, upon request of DHHS for the purpose of audit or evaluation, and is limited only to DHHS employees involved in Study evaluation.

Are there any costs for participating in this research?

There is no cost to you to participate in this beta test.

Will I be paid for my participation in this research?

You will be compensated for the time you spend taking part in this beta test. For completion of the beta test, you will get one $50 in gift card for each session (the initial session where you will be shown how to use the application and the interview).

What else do I need to know?

This research is being funded by National Institutes of Health.

Agreement

Participants who agree to test PositiveLinks must read and verbally agree to the terms below in order to use the PositiveLinks app on a mobile device and receive other program services.

Terms:

_____ **I WILL NOT use PositiveLinks to communicate if there is an emergency**. If there is an emergency, I agree to call 911 or go to the ER.

_____ I understand that PositiveLinks is not a program through which clinical diagnoses, treatment recommendations, or treatment are provided.

_____ I understand that I will receive three check-ins through PositiveLinks each day: “Have you taken your meds yet?”; “What is your stress level right now?”; “How are you feeling?” I will also receive a weekly quiz question that will be informational or entertaining in nature.

_____ I understand there is a community board I can use to post comments or ask questions of other PositiveLinks members. Personal reflections and ideas are welcome. At no time should the community board be used to make insulting or rude comments towards PL members or staff. In addition, promotion of any political candidate is not allowed.

_____ I understand and acknowledge that the community board is monitored by PL staff to ensure these rules are followed.

_____ I understand that posts violating these rules will be taken down by PL staff, and we will discuss those posts with that member. Violation of these rules may result in a 10-day suspension from the board or permanent removal from the board. These decisions are determined by PL staff on a case by case basis.

_____ **I WILL NOT post personally identifying information-- including mine or anyone else's name, phone number, address, or social media information-- on the PositiveLinks community board.** The community board is a space where members can share information anonymously and I will respect the privacy of others posting on the board. In the event I post personally identifying information on the board, the GWU and UVA study teams cannot guarantee immediate removal of the content and I understand that other members would be able to see that information.

_____ I understand that only PositiveLinks members and program staff will have access to the community board. Other care providers will not have access to posts on the community board and this is not a means to communicate with your providers.

_____ I understand that I will have access to resources and answers to frequently asked questions. The resources will include links, videos, and audio files on topics like stress reduction, mindfulness, financial wellness, and general HIV information.

_____ I understand that I will have access to a contact list for the clinic and I will be able to send private messages through the PositiveLinks platform to staff listed in the contacts. The clinic staff member will be able to send a reply to my PositiveLinks inbox.

_____ I understand that normal operating hours for the clinic are Monday through Friday 8am to 5pm. If I message outside of these hours, or if a staff member is out of the office or with another patient, I understand that they may not respond until they are next

available. Study clinic staff may take up to 48 hours to respond to my message and I agree to call the clinic with all time-sensitive needs.

_____ I understand that I will have access to a documents feature that will allow me to upload images to providers at the clinic. During the image capture process, images will not be stored to my phone and will only store within the PositiveLinks app. I understand that to ensure my provider receives my upload I will share the document with them and inform them of the upload.

_____ I understand that the PositiveLinks mobile platform requires a password to access and has other security features to protect my information in PositiveLinks. The password is unique for each member and I will only be able to change it by calling a PositiveLinks staff member. I will not share my password with others.

_____ I understand that I can revoke my agreement to these terms at any time with or without reason. To remove myself from the study I will notify the clinic staff, in person or over the phone, that I am withdrawing from the beta test.

_____ I understand that if I do not abide by the terms in this agreement my participation and continued receipt of PositiveLinks services will be reviewed and may be suspended or terminated as determined by the PositiveLinks Coordinator.

Consent:

By signing below, you agree that the above information has been explained to you and you have had the opportunity to ask questions. You understand that you may ask questions about any aspect of this research during the course of the study and in the future. Your signature documents your permission to take part in this research.

_____ _____ _____

Printed name of participant Signature of participant Date

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

_____ _____ _____

Person obtaining consent Signature of person obtaining consent Date