Aim 1 Informed Consent for Focus Group with DC Cohort Executive Committee Members

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 retention in care and viral suppression among people living with HIV (PLWH). This page will give you key information to help you decide whether or not you want to participate in this study. More 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 complete a survey and participate in a focus group to get your collect your opinions on barriers to retention in care and viral suppression, to elicit input on app features most relevant for patients, and to suggest modifications most useful for retention in care.

Taking part in this study may help researchers and health care providers learn more about the app features that might best support PLWH to improve retention in care and viral suppression. This information will be used to modify and refine the smartphone app, to plan and create health programs, and to create new ways of improving retention in care and viral suppression among PLWH. Your participation in this research will last about 2 hours.

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

You will not benefit directly by being in this study.

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 provider at a participating DC Cohort clinic.

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 people living with HIV (PLWH). Information collected in this research study will be used to:

- Determine barriers to retention in care and viral suppression
- Determine what app features are most relevant for patients
- Inform modification 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 up to 2 hours.

How many people will take part in this research study?

We expect about 20 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 complete a 10-minute survey in REDCap and take part in a 60-90 minute focus group discussion. We will ask about your opinions on barriers to retention in care and viral suppression, your opinions on app features most relevant for patients, and your suggested modifications most useful for retention in care.

2. The focus group session may take place via Zoom or WebEx and will be audio recorded to make sure that your responses are complete and correct. The audio recording that comes from the focus group 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 connected to your name or identifying information.

3. The survey will not be linked to your identity. During the focus group discussion, we will give you a pseudonym to help protect your information. Every effort will be made to keep your protect your information, however, this cannot be promised and there is the possible risk that someone will find out you took part in the focus groups. 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.

4. The focus group discussion will be confidential and whatever is shared here should not be discussed outside of this group. If you recognize some of the other participants, do not give away any information about them or views presented by them. By participating in this focus group, you are agreeing to maintain the confidentiality of the information discussed here today.

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 end 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 learn new approaches that optimize HIV care among patients from other providers. Sharing your knowledge, attitudes, and beliefs may help UVA, GWU, and health care providers to learn more about the app features that might best support PLWH to improve retention in care and viral suppression. This information will be used to modify and refine the smartphone app, to plan and create

health programs, and to create new ways of improving retention in care and viral suppression among PLWH.

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 teams will take special care to protect the information you provide. Your responses will not be associated with your name. Surveys will be labeled with a survey ID. During the focus group you will only be identified by a pseudonym. No one except the study staff at UVA and GWU will have access to the information provided in this focus group. Your responses will be grouped with focus group responses from other persons participating in the group. Direct quotes from this focus group may be used in reports or transcripts. However, no personal identifiers will be used, and the format would include language such as “A member of the focus group 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. You will be asked not to give your real name to any members of the focus group.
2. The digital recording will be stored in a secured file on a computer. Survey data will be securely stored at GWU. Only specific members of the study staff will have access to the file and survey data.
3. Your name or other identifying information will not be included on or associated with any publication of the research.
4. 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 in the focus group you will not be punished 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 focus group.

Will I be paid for my participation in this research?

You will not be compensated for your participation in this study.

What else do I need to know?

This research is being funded by National Institutes of Health.

Agreement

To ensure confidentiality your signature is not required. A copy will be emailed to you if you request it.

Your willingness to participate in this research study is implied if you proceed.