APPENDIX D: Verbal Informed Consent Script to be a 2ADoPT Research Participant

OMB #0920-1091
Expiration Date: 09/30/2021

Title: Assessing the acceptability and adoptability of HIV-1 pre-exposure prophylaxis technologies with and without contraceptive formulation among African American women in the southeastern United States (2ADoPT)

Principal Investigator: Alisú Schoua-Glusberg

Funding Source: Centers for Disease Control and Prevention (CDC)

Flesch-Kincaid Reading Level: 8.2

INTRODUCTION

You are being asked to be in a research study. Before making your decision, please:

- Listen carefully to what I tell you about what the study involves.
- Ask questions about anything that is not clear.

Feel free to take your time to think about whether you would like to participate.

Present Key Information for You to Consider showcard

Key Information for You to Consider
Voluntary consent. You are being asked to volunteer for a research study. It is up to you whether you to choose to participate or not. There is no penalty or loss of benefits, to which you are otherwise entitled, if you choose not to participate or discontinue participation.
Purpose. This research study will examine acceptability (willingness to use the product) and adoptability (whether a product meets women's needs and would be used by women) of a small selection of medical products that were designed for preventing HIV infection.
Duration. You will be asked to take part in a one-time virtual interview. The interview will last about 70 minutes. The first part of the interview will take about an hour to complete. After the interview, a brief questionnaire about you and your health will take about an extra 6 minutes to complete.
Procedures and activities. • Your name and contact information will be kept secure and separate. o Your name will not be used to identify your interview. A study identification number will be assigned to all of your interview information. • The interview is done over the Internet using Zoom. o The interview is audio recorded. Only audio information from the interview is recorded and saved. • You will be asked a brief set of questions about you and your health. o Your answers will be entered into a computer.
Risks. Like many research studies, there are some risks to participating in this research study. Some questions may make you feel uncomfortable or embarrassed.
Benefits. Taking part in this study may have no direct benefit to you. The study will not provide you with general medical care.
Alternatives. You are free to choose not to participate in this research. If you choose to participate, you may choose not to answer any questions that make you uncomfortable.
Contact. If you have any questions about this study or your part in it, contact: • Dr. Alisú Schoua-Glusberg at alisu@researchsupportservices.com or 1-847-864-5677 • CDC's Deputy Associate Director for Science at 1-800-584-8814 o Reference CDC protocol number #7214

VOLUNTARY PARTICIPATION AND WITHDRAWAL FROM THE STUDY

Your participation in this study is voluntary. This means it is completely up to you to be in this study. By agreeing to take part in this study, you will not give up any legal rights. You have the right to leave this study at any time without penalty.

- You may refuse to do anything you do not feel comfortable with or refuse to answer any questions that you do not want to answer.
- You can stop being in the study even after you have agreed to participate.
- Your decision will not affect the care, treatment, or services that you are getting right now and will not affect any care, treatment, or services that you may decide to get later.

We may ask you to stop being in the study at any time if we think that:

- Participation is not in your best interest;
- You are not following study instructions; or
- You are having trouble with the interview.

STUDY OVERVIEW

The purpose of this study is to learn what African American women living in the southeastern United States think about medical products for preventing HIV infection. Some of these products may also offer protection against pregnancy.

The study will help to better understand acceptance toward these medical products and learn how these medical products can best meet the needs of African American women.

The study will take place with women in three cities:

- Atlanta (Georgia),
- Jackson (Mississippi), and
- Baton Rouge (Louisiana)

We plan to interview at total of 75 African American women. Twenty-five interviews will be done in each city.

DURATION

You will be asked to take part in a one-time virtual interview. The interview will require about 70 minutes of your time. The first part of the interview will take about an hour to complete. A brief questionnaire about you and your health will take an extra 6 minutes to complete.

PROCEDURES

If you decide to be in the study, you will be asked to take part in a virtual interview. The interview is done over the Internet using Zoom, a video-conferencing system.

The first part of the interview will be audio recorded. I will ask you to say on the audio recording that you agree to take part.

Only audio information from the interview is recorded and saved. You will then be asked a brief set of questions about you and your health. This part of the interview will not be audio recorded. Instead, I will enter your answers into a computer.

When the interview is over, the audio recording will be typed into a written document called a transcript. When we prepare the transcript, we will not include your name or the names of other people that you might talk about during the course of your interview. After the study is over and the audio recordings have been transcribed, we will destroy the recording of your interview.

RISKS AND DISCOMFORTS

Some of the questions might make you feel uncomfortable. You do not have to answer any questions that make you feel uneasy. If something comes up for you that you want to know more about or you think is a problem in your life that you need help with – like depression – we can give you the names of places that can help you.

The greatest risk to you is an unplanned release of your private information. To prevent this from happening, we will assign you a study identification number. Your name will not be used on any study forms except the contact form, which will be kept secure and separate from your interview and other study documents. All research documents and audio recordings will be kept in a locked and secure place. Your interview audio recording and transcript will be kept in a secure, password-protected file and only study staff will have access to your information.

IN CASE OF INJURY

If you believe you have become injured from this taking part in this interview, you should contact Dr. Alisú Schoua-Glusberg at telephone number 1-847-864-5677.

BENEFITS

This study is not designed to benefit you directly. You will receive information at the end of the interview about services available in your community, including HIV testing. The study results may be used to help others in the future. There may be no direct benefit to you as a participant in this study.

STUDY INCENTIVE

You will receive $40 as an incentive for participating in this study.

COSTS TO YOU

The only costs to you are:

- Your time;
- Use of your own phone, tablet or laptop to take part in the interview; and
- Use of your own WIFI if the study's temporary WIFI-on demand pass was not used.
    - Your device is not supported by the study's temporary WIFI on-demand pass or you used your own Internet

Participating in this study will not affect the healthcare or services you currently receive or may receive in the future.

HOW YOUR RECORDS WILL BE KEPT PRIVATE

Your information will be kept private. A number, and not your name, will be given to your interview and other study records. Once the study is over, we will destroy the audio recording. Only the typed-out version of the audio recording is kept.

Your name and contact information will not appear when we present this study or publish its results. Your name and contact information will not be shared with CDC staff.

PRIVACY

Government agencies and study staff from RSS and IMPAQ may look at your study records to make sure the study is being run safely and correctly. The Office for Human Research Protections, CDC (the government agency funding this study) may also look at your study records.

RSS and IMPAQ will keep the study documents private to the extent we are required to do so by law. Your interview will not be presented alone. What you tell us will be added to what we hear in other interviews. The reports from this study will be shared with your community.

CONTACT INFORMATION

Call Dr. Alisú Schoua-Glusberg at alisu@researchsupportservices.com or 1-847-864-5677:

- If you have any questions about this study or your part in it, or
- If you have questions, concerns, or complaints about the research

You may also call the office of CDC's Deputy Associate Director for Science at 1-800-584-8814. You can leave complaints or concerns at this number without giving your name and phone number, but please make sure to include CDC protocol number #7214 for this project. If you would like for your call to be returned, please leave a brief message with your name, phone number, and CDC protocol number #7214 for this project.

Do you wish to have a copy of the **Key Information for You to Consider** sheet mailed or emailed to you?
[ ] Yes [ ] No

Was verbal informed consent given?
[ ] Yes [ ] No