

Attachment 4 Written Informed Consent Form

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

Consent to be a Research Subject

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: 8.0

INTRODUCTION

You are being asked to be in a research study. This form is designed to tell you the things you need to think about before you decide if you want to be in the study. It is entirely your choice. If you decide to take part, you can change your mind later on and leave the research study. You can skip any questions that you do not wish to answer.

Before making your decision:

- Please carefully read this form or have it read to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form to keep. Feel free to take your time to think about whether you would like to participate. By signing this form, you will not give up any legal rights.

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 take place in three cities: Atlanta (Georgia), Jackson (Mississippi), and Baton Rouge (Louisiana). The study team will interview 75 African American women. Twenty-five interviews will be done at each site. The study will help CDC better understand acceptance toward these medical products and learn how these medical products can best meet the needs of African American women.

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 choose to participate or not. There will be 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 interview. The interview will last about an hour.

Procedures and activities. To participate in the study, you will have to complete an audio-recorded interview.

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.

PROCEDURES

We are asking you to join a research study. This form tells you what you need to know before you decide to be in this study. It is completely up to you if you want to be in this study. If you decide not to be in this study, you can stop at any time. If you decide to be in the study, you will be asked to take part in an interview that will last about 70 minutes. You can skip any questions that you do not want to answer. Participating in this study will not affect the healthcare or services you currently receive or may receive in the future. If you decide that you do not want to be in the study anymore, please tell the person who is interviewing you and they will stop.

AUDIO RECORDING

With your permission, your interview will be audio-recorded. The person who does the interview will also take notes. 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 file cabinet in a secure place. Your interview audio recording and transcript will be kept in a secure, password-protected file and only authorized 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 CONSIDERATION

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

COSTS TO YOU

Other than your time, there will be no cost to you to take part in this study.

HOW YOUR RECORDS WILL BE KEPT PRIVATE

Your information will be kept private. If you agree to take part in this study, we will ask you to sign your name on this document and the receipt for your incentive. We will ask you to say on the audio recording that you agree to take part. A number, and not your name, will be given to your records. We will listen to the audio recording and type out what you say. Once the study is over, we will destroy the audio recording.

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. All answers that you give will be kept private. 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.

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.

VOLUNTARY PARTICIPATION AND WITHDRAWAL FROM THE STUDY

You have the right to leave a study at any time without penalty. Your participation in this study is voluntary. This means it is completely up to you to be in this study. You can stop being in the study even after you agree to be in the interview. 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. 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 decide that participation is not in your best interest. If we think that you are not following study instructions or having trouble with the interview, we might ask you to stop participating in this study.

CONTACT INFORMATION

Contact 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 contact the office of CDC’s Deputy Associate Director for Science at 1-800-584-8814 where you can leave a brief message with your name, phone number, and CDC protocol number #7214 for this project. If you can also leave complaints or concerns at this number without giving your name and phone number. Please make sure to include CDC protocol number #7214 for this project.

CONSENT

Please print your name and sign below if you agree to be in this study. By signing this consent form, you will not give up any of your legal rights. We will give you a copy of the signed consent to keep.

Signature of Subject

Date Time

Signature of Person Conducting Informed Consent Discussion

Date Time