Form Approved
OMB No. 0920-New
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Understanding Decisions and Barriers about PrEP Use and Uptake Among Men Who Have Sex With Men

Attachment # 4a

In-depth Interview Informed Consent

Prepare 4 PrEP
Consent to be a Research Subject
Phase 1: In-Depth Interview and Behavioral Assessment

Study Title

Prepare 4 PrEP: Understanding decisions of gay, bisexual, and other who have sex with men about using Pre-Exposure Prophylaxis (PrEP) to prevent HIV infection.

Introduction

The Centers for Disease Control and Prevention, in collaboration with Research Support Services, Inc., IMPAQ International, LLC, and Emory University, is asking you to join a research study to talk about pre-exposure prophylaxis, or PrEP, a daily pill to prevent HIV. 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. The results will be used to improve HIV prevention for gay, bisexual and other men who have sex with men.

Study Overview

We are doing this study because we want to learn more about why some men decide not to take PrEP, or why they start PrEP but end up stopping. We want to understand the barriers and challenges men experience when they think about using PrEP. We asked you to be in this study because you are a gay, bisexual, or other man who has sex with men, and you are eligible to take PrEP. For the study, we will talk to 300 people in 3 cities: Atlanta, GA, Chicago, IL, and Raleigh-Durham, NC.

Procedures

We are asking you to take part in a 45-minute face-to-face interview and a 30-minute behavioral assessment.

1. **Interview.** We will ask you questions about PrEP, HIV and STDs, sexual risk behavior, and about other HIV prevention options. We will also ask about your experiences when offered PrEP, or starting on PrEP, and what made you decide to use it or not. The interview will be recorded and the interviewer will take notes.
2. **Behavioral Assessment.** After you finish the interview, you will answer survey questions using a tablet or other electronic device we will provide. The survey takes about 30 minutes. There are questions about sexual behavior, PrEP and condom use, future HIV prevention options, and general health behavior. You can answer the questions at your own pace. The survey will allow you leave a question unanswered but will ask you to confirm that you did not answer before moving to the next question. Study staff will be available to help if you have questions or technical issues.

Benefits & Risks

There are no direct benefits to you for taking part in this study. It might help you to tell your opinions to someone who wants to hear what you have to say. You might enjoy knowing that what you say will be used to improve HIV prevention programs for gay, bisexual, and other men who have sex with men.

There is no risk that we know about if you take part in this study. Some of the questions might make you feel uncomfortable. You do not have to answer any questions that make you feel uneasy or uncomfortable. 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 organizations that are close to where you live and can help you. The greatest risk to you is a breach of your privacy. In order to prevent this from happening, we will assign you a study identification number. We will use this number instead of your name on all study forms.

Token of Appreciation

You will receive $60 as a token of appreciation for completing the interview and electronic survey. Except for your travel and interview time, there will be no costs to you as a result of taking part in this study.

Privacy

We will do everything we can to protect your privacy to the extent allowed by law. In order to reach you we have your name, contact information, and your study number. This information is kept in a locked file cabinet separate from our study records. This information will be destroyed at the end of the study.

If you decide to participate, we will give you a code and this will be used instead of your name on the interview and survey. Your interview notes and audio recordings will be kept in a locked file cabinet in a secure place and are only accessible to study staff. When we write up your interview, we will remove any names you might use. Your answers to the survey questions will be kept in a database on secure servers and in password-protected files. Your name and other facts that might point to you will not appear when we present this study or publish its results. After the study is over, we will destroy the audio recording of your interview.

What if I have questions?

If you have any questions about this study or if you feel you have been harmed, please call Dr. Alisu Schoua-Glusberg at 888-540-6770. If you have any questions about your rights as a participant in this study, please contact CDC/ATSDR's Deputy Associate Director for Science at 1-800-584-8814. Leave a message with your name, phone number, and refer to CDC protocol # 7031, and someone will call you back.

What if I decide I do not want to be in this study?

Your participation in this study is voluntary. That means it is completely up to you to be in this study. You can refuse to be in this study at any time. You can stop being in this study even after you agree to be in the interview. Your decision has no effect on the care, treatment, or services that you get right now or any services that you might get later. We may ask you to stop being in the study at any time if we decide that it is in your best interest. If we think that you are not following study instructions, or having trouble with the interview or survey, we might ask you to stop participating in this study.

We will give you a copy of this consent form to keep.

If you are willing to volunteer for this research, please sign below.

_____	_____	_____
Subject's Signature	Date	Time
_____	_____	_____
Person Obtaining Consent	Date	Time