

Form Approved
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Understanding Decisions and Barriers about PrEP Use and Uptake Among
Men Who Have Sex With Men

Attachment # 4b

Focus Group Informed Consent

Public reporting burden of this collection of information is estimated to average 5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; Attn: OMB-PRA (0920-New)

Prepare 4 PrEP
Consent to be a Research Subject
Phase 1: Focus Group 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 on 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 60-minute focus group and a 30-minute behavioral assessment.

1. **Focus group discussion.** We will ask you questions about PrEP, the impact of PrEP for gay and bisexual men, sexual risk reduction, and other HIV prevention options. The focus group will be recorded and the facilitator will take notes.
2. **Behavioral Assessment.** After the focus group, 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. While we will ask that participants not share comments heard in the focus group discussion with anyone outside of the focus group, a focus group participant may not honor this request.

Token of Appreciation

You will receive \$75 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.

During the focus group, we will ask you not to use names when you talk about people. You can say things like ‘my mother’ or ‘my friend’ instead. None of the focus group transcripts that we use will have your name on them. Instead of your name, we will use a code number. We will use that number for the focus group and the survey. Focus group 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 the focus group, we will remove any names you or others might use. Your answers to the survey questions will be kept in a secure 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 focus group.

What if I have questions?

If you have any questions about this study or feel you have been harmed, please 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 focus group. 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 focus group 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