

Understanding Barriers and Facilitators to HIV prevention for  
Men Who Have Sex with Men (MSM) – Pulse Study

**Attachment 4a    HIV-Negative MSM Consent Form English**

## **Emory University/Research Support Services Inc. Consent to be a Research Subject**

**Study Title:** Understanding Barriers and Facilitators to HIV Prevention for Men Who Have Sex with Men (MSM)

**Principal Investigator:** Paula M. Frew, PhD, MA, MPH

**Sponsor's Name:** Centers for Disease Control and Prevention

### **What is the Purpose of this Study?**

We are doing this study because we want to learn about how men get or do not get HIV if they have sex with other men. We want to know more about how HIV impacts men, how they avoid getting HIV, and what they think about how to protect themselves against HIV, such as taking pills and using condoms. We asked you to be in this study because you are a man who has sex with other men and you do not have HIV. For the study, we will talk to 150 people in five different cities. These conversations will help us understand how to help some men not get HIV.

### **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 to be in the study, you can stop at any time. You can skip any questions that you do not want to answer. Participating in this study will not affect the healthcare you currently receive or may receive in the future. If you decide that you do not want to be in the study any more, please tell the person who is interviewing you.

### **How will the interview be done?**

This interview takes about 1 hour. We are going to ask you questions about how HIV affects you and your community, and what you think about different ways to protect yourself. We will ask you about how you think other people keep from getting HIV. If you are in the study, you will receive \$40 in the form of a gift card or cash. Even if you choose not to complete the study, we will give you the full \$40 in the form of a gift card or cash.

### **Audio recording:**

The interview will be recorded. The person who does the interview will also take notes. When the interview is over, we will write it up. When we write up your interview, we will not use your name or the names of other people you might talk about. After the study is over, we will destroy the recording that has your interview.

### **What are the benefits to me?**

There are no direct benefits to you for participating 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 make programs to help keep other men like you safe from HIV.

### **What are risks to me?**

There is no risk that we know about if you participate 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 are 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 confidentiality. In order to prevent this from happening, we will assign you a study identification number. Your name will not be used on any study forms. All research documents and audio recordings will be kept in a locked file cabinet in a secure place. When we type up your interview, we will not use your name and we will take out any names you say. Your interview will be kept in a password protected file and only authorized staff can access your information.

**What is the cost of joining this study?**

There are no costs to you for joining the study.

**Confidentiality**

Certain offices and people other than the researchers may look at study records. Government agencies and Emory employees overseeing proper study conduct may look at your study records. These offices include the Office for Human Research Protections, the funder(s), the Emory Institutional Review Board. Emory will keep any research records we create private to the extent we are required to do so by law. A study number rather than your name will be used on study records. In order to reach you we have your name, contact information, and your study number. That information is kept locked separately from our study records in the office. Outside of the office your name and contact information will not have a study number. Your name and other facts that might point to you will not appear when we present this study or publish its results. We will do everything we can to keep others from learning about your participation in the research.

**Authorization to Use and Disclose Protected Health Information**

The privacy of your health information is important to us. We call your health information that identifies you, your “protected health information” or “PHI.” To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the “Privacy Rules.” Here we let you know how we will use and disclose your PHI for the study.

**PHI that Will be Used/Disclosed:**

The PHI that we will use or share for the main research study includes HIV status.

**Purposes for Which Your PHI Will be Used/Disclosed:**

We will use your PHI for conducting research. Your HIV status will help us to determine your eligibility for this study, and will guide the questions that we ask during the interview.

**Use and Disclosure of Your Information That is Required by Law:**

All answers that you give will be kept private. This is so because this study has been given a Certificate of Confidentiality. This means anything you tell us will not have to be given out to anyone, even if a court orders us to do so, unless you say it's okay. But under the law, we must report to the proper authorities suspected cases of child abuse or if you tell us you are planning to cause serious harm to yourself or others.

**Authorization to Use PHI is Required to Participate:**

By signing this form, you give us permission to use and share your PHI as described in this document. If you do not authorize the use of your PHI for the interview, you will not be interviewed.

**People Who will Use/Disclose Your PHI:**

The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study.
- The Centers for Disease Control and Prevention is the sponsor of the study. The Sponsor will NOT have access to your PHI.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
  - Emory offices that are part of the Human Research Participant Protection Program and those that are involved in study administration. These include the Emory IRB.

**What if I'm hurt?**

Emory and the sponsor have not set aside any money to pay you or to pay for medical treatment if you are injured during the course of the interview. If you believe you have become ill or injured from the interview, you should contact Dr. Paula Frew at 404-712-8546. You should also let any healthcare provider who treats you know that you joined this interview study.

**What if I have Questions?**

If you have any questions about this study, please call Dr. Paula Frew at 404-712-8546. You can also write Dr. Paula Frew. Her address is 500 Irvin Court, Suite 200, Decatur, GA 30030. Her email is [pfrew@emory.edu](mailto:pfrew@emory.edu).

If you have questions about your rights as a participant in a research study, please call the Emory University Institutional Review Board at 404-712-0720 or 1-877-503-9797.

**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

Study No.: «ID»

**Emory University IRB**  
IRB use only

Document Approved On: «ApproveDate»

following study instructions, or having trouble with the interview, 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 name (Please Print)

\_\_\_\_\_  
Subject's Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Time

\_\_\_\_\_  
Person Obtaining Consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Time