**Form Approved**

**OMB No. 0920-XXXX**

**Expiration Date: XX/XX/XXXX**

**Evaluation of Free Rapid HIV self-testing in MSM (eSTAMP): Randomized-Controlled Trial**

**Attachment 4b**

**Focus Group Consent Form**

Public reporting burden of this collection of information is estimated to average 10 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-XXXX)

**Emory University, Rollins School of Public Health**

**Consent to be a Research Subject**

**Flesch-Kincaid Reading Level: 7.9**

**Title**: Evaluation of Rapid HIV Self-Testing among MSM in High Prevalence Cities

**Principal Investigator:** Patrick Sullivan, DVM PhD

**Funding Sources:** Emory University and MANILA Consulting Group, Inc. are conducting the study, which is funded by the Centers for Disease Control and Prevention (CDC).

Introduction

You are invited to be in a research study being done by Emory University’s Rollins School of Public Health and Manila Consulting Group, Inc., and sponsored by the Centers for Disease Control and Prevention. You are being asked because you recently were in our home HIV testing study. We are now doing focus groups to find out about men’s experience in the study. We expect to have 10-12 men in the focus group.

Purpose

This study will find out what men thought about being in an online HIV study and what they think about testing for HIV at home. The focus group is to talk about why you decided to take part and if you used or gave away any of the home test kits. We will also ask you about when and why you used the test kits.

Procedures

When you came here you were given a number. If we pick you to be in the focus group, you will be called by your number. You will be invited into a secure room where the focus group will take place. Before the focus group starts, the leader will discuss the consent. You will then have the chance to ask any questions and make sure everyone is comfortable with the process.

The focus group will take about 1.5 hours and will be audio recorded and recorded by a note-taker. The tapes and written notes will be destroyed after transcription of the focus group. The study team will ask you about your experiences being in a study about home HIV testing. You will be asked about the types of tests you used, which ones you gave away, and if you would use them again.

We have a toll-free number for any concerns that you may have with the study or study staff. The number is at the bottom of this form.

Risks and Discomforts

We do not expect there to be any risks or discomforts in this study. However, this is a group discussion, and we cannot be certain that others in the group will not discuss what was said. You will be asked about taking part in the home HIV testing study and receiving HIV test kits for use at home. You may feel uneasy talking about these issues. You can choose not to answer any of the questions asked.

Benefits

Taking part in this study may not benefit you directly. Researchers will learn new things that will help them better design future HIV studies and improve the health of men in our community.

Token of Appreciation

If you decide to take part in the focus group you will receive $50.

Privacy

Any contact information that you provided us is stored in a password-protected database accessible only by study staff. We got your contact information to get in touch with you for the focus group because you were in the home HIV testing study. No names will be used in the focus group. We will record the focus group to allow the researchers to listen later and to identify the main issues. The tapes will be stored in a locked cabinet where only the study staff will have access to them. We will transcribe the tapes within 4 weeks and then destroy the tapes and the written notes. If a name or any other personal information is said by accident, we will not include it in the transcription. Agencies and Emory departments and committees that make rules and policy about how research is done have the right to review these records. So do companies and agencies that pay for the study. This includes MANILA Consulting Group, Inc. and the CDC. We will keep all records private to the extent that we are required to do so by law.

Voluntary Participation and Withdrawal

Being in this research is voluntary. You have the right to refuse to be in this focus group. You can stop at any time after giving your consent without losing benefits that you are otherwise entitled to. The researcher may stop you from taking part in this study at any time if he/she decides it is in your best interest, if you do not follow study instructions, or if anyone’s behavior becomes disruptive.

Contact Persons

If you have any questions about this study or feel you have been harmed in this study please contact a member of the research team:

Patrick Sullivan, DVM PhD

Emory University

Rollins School of Public Health

1518 Clifton Road NE

Room 464

Atlanta, GA 30322

(404) 727-2038

pssulli@emory.edu

If you have any questions about your rights as a participant in this study or feel you have been harmed by being in this study you can contact the institutional review board at Emory University.

For Emory University contact:

Emory IRB

1599 Clifton Road

5th Floor East

Atlanta, GA 30322 USA

Tel: 404 712 0720

Toll free: 877 503 9797

Email:irb@emory.edu

You may keep a copy of this form for your records if you like.

If you agree to the above and would like to participate in this study, please give your verbal consent and the study staff will sign below.

|  |  |  |
| --- | --- | --- |
| Participant Number |  |  |
|  |  |  |
| Printed name of Person Obtaining Consent |  |  |
|  |  |  |
| Signature of Person Obtaining Consent | Date | Time |