

Evaluation of Rapid HIV Self-Testing: Qualitative and User Proficiency Assessments

Generic Information Collection Request under 0920-0840

Attachment 2b.

Focus Group Consent Form

Emory University, Rollins School of Public Health

Consent to be a Research Subject

Title: Evaluation of Rapid HIV Self-Testing: Qualitative and User Proficiency Assessments

Principal Investigator: Patrick Sullivan, DVM PhD

Funding Sources: Emory University, Centers for Disease Control and Prevention (CDC), MANILA Consulting Group, Inc.

Introduction

You are invited to be in a research study being done by Emory University's Rollins School of Public Health. You are being asked because you have told us that you are a man who has sex with men who is over 18 years of age. We expect to have 60 men taking part in the focus group. If you decide to take part, the things we learn from you today will help improve a men's health study.

Purpose

To plan for a study on HIV home testing among men who have sex with men (MSM), we want to know how we can make the best packages for HIV home test kits and how we can make the online study easy for men to participate. This study will find out what men think about being in an online HIV study and what they think about testing for HIV at home.

The focus group is to get your thoughts on how willing MSM are to use at-home HIV test kits, kind of like tests that women use to check if they are pregnant. We are not asking you to be in the actual study at this time; we just want you to share your ideas that will help us best create test kit packages that will be used at a later time.

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 and 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. We will also give you a toll-free number for any concerns that you may have with the focus group or the study staff.

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 how you would feel about being asked to be in an online HIV study and how you would feel about taking part. You will also be shown packages of HIV home test kits that may be sent to participants in an online study. You will be asked what you like and don't like about them. You will also be asked about the types of tests that may be used in the study, if you would be likely to use them, and who, if anyone, you would likely give these test kits to.

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 an online HIV 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 personally, but researchers will learn new things that will help them better design the online HIV study and improve the health of MSM.

Token of Appreciation

If you decide to take part in the focus group you will be given \$50.

Privacy

We will not collect any information that will identify you. We got your contact information to get in touch with you for the focus group; after contacting you this information was destroyed. No names will be used in the focus group. We will record the focus group to allow the researchers to listen to them 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 10 days 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 which includes MANILA Consulting Group, Inc. and CDC. We will keep all records that we produce private to the extent we are required to do so by law.

Voluntary Participation and Withdrawal

Being in this research is voluntary and 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 others' 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

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