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

Generic Information Collection Request under 0920-0840

Attachment 2c.

In-Depth Interview 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 up to 20 men taking part in these interviews. 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 instructions for using HIV home test kits easy for men to follow. This study will find out if men understand how to use the HIV home test kits we want to use in the study. We are not asking you to be in the actual study at this time; the things you tell us will help us make home 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 interviewed, you will be called by your number to go into a secure room where the interview will take place. Before the interview starts, the interviewer will discuss the consent. You will then have the chance to ask any questions and make sure you are comfortable with the process. We will give you a toll-free number for any concerns that you may have with the study or study staff.

The interview will take about 1 hours and will be audio and video recorded so the researchers can view and listen to the interview at a later date. The tapes will be destroyed after transcription of the interview. Participants will be asked to interact with the test kit package and each test and describe their understanding of how to do each test. They won't actually test themselves; they will just talk through what they understand study participants will do. They will be asked to share ideas about how the instructions could be more clear and how the packaging could be changed so that men will be comfortable using the test kits.

Risks and Discomforts

We do not expect there to be any risks or discomforts in this study. You will be asked questions about taking part in an online HIV study and receiving HIV test kits for use at home. You may feel uncomfortable 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 you will be given $50.

Privacy

We will not collect any information that will identify you personally. We got your contact information to get in touch with you for the interview; after contacting you this information was destroyed. No names will be used in the interview. We will record the interview to allow the researchers to watch and listen to 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. 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 participate. 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 or if you do not follow study instructions.

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 research 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 information and would like to be in this study, please give your verbal agreement and the study staff will sign below.

Participant Number

Printed name of Person Obtaining Consent

Signature of Person Obtaining Consent | Date | Time