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

Attachment 2d

Proficiency Assessment 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 40 men taking part in this research. 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 if men can easily 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 improve the home test kit instructions that will be used at a later time.

Procedures

You will be given a testing kit package that you will open and conduct the testing process following the kit instructions. Written instructions are included with each individual test and there will also be access to an electronic application that will provide video instructions and timers for each test. After each rapid test is done and interpreted by the participant, a study staff member trained in HIV testing will interpret the test results. You will also collect and prepare a dried blood spot specimen for shipping. After the self-testing, you will complete a survey about the self-testing process, and you will use an electronic application to review a panel of test result images. At the end of the session, you will have the option to receive counselor provided HIV screening from trained Emory staff and to speak to the trained HIV counselor or other study staff.

The testing will take about 1.5 hours and will be audio and video recorded. The tapes will be destroyed after any transcription of the interview. You will be asked to do 2 self-tests and collect a few drops of blood. You will record their test results on paper and in an electronic application. A trained tester will also read the results. You will be asked to share ideas about how the instructions could be more clear. After each test you will view test results in an electronic application and record the result of each test.

Those who test positive on any of the self-tests or the post-test during the study will be offered HIV counseling and testing by trained Emory staff. This is a voluntary service that the participant can accept or not. Information will be collected by the Emory staff for HIV reporting purposes (name, mailing address and phone number) and if they are confirmed HIV-positive, this information will be reported by telephone to the Georgia Department of Public Health. This information remains private when it is reported to the state health department. If the confirmatory testing is negative, this information will be destroyed. We will also give you a toll-free number for any concerns that you may have with the study or study staff. If we pick you to take part, you will go into a secure room where the session will take place. Before the testing starts, the study staff will discuss the consent. You will then have the chance to ask any questions and make sure you are comfortable with the process.

Risks and Discomforts

We do not expect there to be any risks. There may be minor discomfort from the finger-stick HIV tests and bruising may occur. You may feel uneasy talking about HIV. You can choose not to answer any of the questions asked.

Benefits

Subjects will learn their current HIV status based upon a self-test or from a trained counselor if they accept the additional testing service. There are no additional direct benefits to the participant of participation in the research, 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 $75 for completing the self-testing activities for this study. You will not receive a token of appreciation for the voluntary HIV testing provided by Emory University.

Privacy

We will not collect any information that will identify you personally. No names will be used in the session. We will record the session 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 mistake, 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.

If any test result is preliminarily positive, you will be offered HIV counseling and testing by trained Emory staff. This is a voluntary service that you can accept or not. Information will be collected by the Emory staff for HIV reporting purposes (name, mailing address and phone number) and if you are confirmed HIV-positive, this information will be reported by telephone to the Georgia Department of Public Health. This information remains confidential when it is reported to the state health department. If the confirmatory testing is negative, this information will be destroyed.

Voluntary Participation and Withdrawal

Being in this research is voluntary and you have the right to refuse to take part. You can stop at any time after giving your consent without losing benefits that you are otherwise entitled to. Study staff may stop you from taking part in this study at any time if they decide 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 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 written agreement below.

Print Volunteer's Name

Signature of Volunteer Date Time

Printed name of Person Obtaining Consent

Signature of Person Obtaining Consent Date Time