Attachment 2a

Field Performance Study Consent Form

Emory University Rollins School of Public Health
Consent to be a Research Subject

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 this study which is sponsored by the Centers for Disease Control and Prevention (CDC).

Introduction
You are invited to be in a research study. This study is being done by Emory University's Rollins School of Public Health. We expect to have up to 1000 men take part. If you decide to take part, the things we learn from you will help create better HIV prevention programs for our community.

Purpose
We are doing this study to help us understand how men who are not trained in HIV testing can test themselves at home. We want to see if men can follow test kit instructions, do the test on their own, and read and report their results.

Procedures
We will first ask you some questions to see if you are eligible to participate. You must be at least 18 years of age to take part in this study. Then we will ask you to provide your contact information and complete an internet survey. The first survey will take about 15 minutes.

We will then send you 2 rapid HIV home test kits. In one test, you swab your mouth and collect an oral fluid sample. In the other test you will prick your finger and collect a drop of blood. Each kit will have written instructions on how to do that test. You can also watch a video online or on a smart phone to see how to use each test. After doing the tests you can report your results and take a follow-up survey. Testing, reporting results and taking the survey will take about 1 hour.

If you have any questions, problems with using the tests, or if you test positive, you can call a toll-free helpline number 24 hours a day, 7 days a week. We will also give you a toll-free number for any concerns that you may have with the study or study staff. Both numbers are at the bottom of this form.

You will also collect and prepare a dried blood spot specimen, and mail it back to us in a pre-paid shipping envelope. This specimen will be tested for HIV at a laboratory and the results will compared with the rapid HIV home test results you reported.

Risks and Discomforts
A rare but possible risk of participating in this study is that someone besides study staff could gain access to your name, mailing address, phone number or email address through receiving a package containing HIV self-test kits, receiving study related emails, receiving text messages, interacting with the online surveys or with study application on a cell phone. This is unlikely and we will take precautions to ensure this does not happen. There may be minor discomfort from pricking your finger to do one HIV test and collecting a dried blood spot specimen. You may feel uneasy while answering some survey questions about HIV. You can choose not to answer any questions that make you feel uneasy.

Benefits

You will learn your current HIV status using free rapid HIV home tests. We will also confirm your results from the lab testing of your dried blood spot specimen. There are no additional direct benefits from participating. The information we gain from this study will help us to design a larger study using rapid HIV home test kits.

Token of Appreciation

If you take part, you can receive up to $60 for completing all study activities. You will receive a token of appreciation by your choice of PayPal or an Amazon.com gift card.

Privacy

Any contact information that you provide us will be stored in a password-protected database accessible only by study staff. Survey data and your results from the rapid HIV home tests will be held in separate password-protected databases. 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.

If your lab test is positive, your contact details will be reported to your state health department by phone. This information remains secure and private when it is reported to the state health department. If your lab test is positive, but you have not reported your rapid HIV home test results, your contact details will still be reported to your state health department. This is required by law. If your rapid HIV home test results and the lab test result do not agree, Emory study staff will contact you by phone. They will provide you with more information and link you to services in the city where you live.

HIPAA Authorization to Use or Disclose Health Information

The privacy of your health information is important to us. In protecting your health information that identifies you, we will follow all requirements of the Health Insurance Portability and Accountability Act ("HIPAA") that apply. This section will let you know how we will use any health information you give us for this study that could possibly identify you. This includes your name, mailing address, phone number and email address. Please read this section carefully and if you agree, "sign" the form at the end.

People That Will Use Or Disclose Your Health Information That Identifies You And Purpose Of Use/Disclosure

The following people and groups will use and disclose your health information in the study. In this form, these are called the "Information Users." These are the Principal Investigator, the research staff and people and groups that help conduct the study. They will use and disclose your health information to do this work.

The CDC is the sponsor of this research. The sponsor and all other people and groups that the sponsor retains to help it conduct and oversee the study may use and disclose your health information. This is to make sure the research is being done correctly and to collect and analyze the results.

There are a number of university persons/units, government agencies and other individuals and groups that may use and disclose your health information. This is to make sure that the research study is being conducted correctly and safely, and to monitor and regulate the research or public health issues. These people and groups include: the Emory University Institutional Review Board; the Emory University Office of Research Compliance; any government agencies who regulate the research including the Office of Human Subjects Research Protections, public health agencies, and your state health department (if your HIV test result is positive).

By "signing" this document you agree to allow any of these Information Users to use or disclose your health information that may identify you in order to conduct the study, or to monitor or regulate research. We will comply with any laws that require us to disclose your health information, such as laws that require us to report child abuse or elder abuse. We may share your health information with a public health authority that the law

authorizes to collect or receive such information for the purpose of preventing or controlling disease, injury or disability and/or conducting public health surveillance, investigations or interventions.

Description Of Health Information That Identifies You That Will Be Used Or Disclosed
The Information Users may use or disclose health information about you from the answers you provide to the survey questions and your HIV test result.

Revoking Your Authorization
Please note that you do not have to "sign" this Authorization. Also, if you do "sign" this Authorization, you may change your mind at any later time and revoke (take back) this Authorization. If you want to revoke this Authorization you must write to:

Patrick Sullivan, DVM, PhD
Emory University Rollins School of Public Health
1518 Clifton Road
Atlanta, GA 30322

If you revoke your Authorization, the researchers will not collect any more health information that identifies you. They may use or disclose identifiable information that you already gave them in order to notify any of the other Information Users that you have taken back your authorization, to maintain the integrity or reliability of the study, and to comply with any law that they are required to obey.

Other Items You Should Know
HIPAA only applies to people or organizations that are health care providers, health care payers or health care clearinghouses. HIPAA may not apply to all Information Users. If HIPAA doesn't apply to an Information User, then that User doesn't have to follow HIPAA requirements when it uses or discloses your health information. You do not have to sign this authorization form, but if you do not, you may not participate in the study.

If your identifying information is removed from your health information, then the information that remains will not be subject to this authorization or covered by HIPAA. It may be used or disclosed to other persons or organizations, and/or for other purposes.

Expiration Date
This authorization will expire when data analysis for this study is complete.

Voluntary Participation and Withdrawal
Being in this research is voluntary and you have the right to refuse to take part. You can stop any time after giving your consent without losing benefits you are otherwise entitled to. Study staff may stop you from taking part at any time if they decide it is in your best interest or if you do not follow instructions.

Contact Information
If you have any questions, problems with using the tests, or if you test positive, you can call this toll-free study support number 24 hours a day, 7 days a week: 1-800-XXX-XXXX.

If you have any questions 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
Atlanta, GA 30322
Telephone: 404.727.2038
Email: 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:

Emory IRB
1599 Clifton Road
5th Floor East
Atlanta, GA 30322 USA
Telephone: 404.712.0720
Toll free number: 877.503.9797
Email: irb@emory.edu

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

Please check ONE of the following options:

I am at least 18 years of age, agree to the above information and would like to participate in this research study.
I would not like to continue as a participant in this research study.

If the participant consents continue to the Eligibility Screener.

* Reading level does not include HIPAA Authorization language.

Consent to Store Samples for Future Use

We would like to freeze part of the DBS specimen you send us for future use. Your samples would be stored for an indefinite time. We may use these specimens for research in the future. Nothing that could be linked to you will be kept with the specimens. Tests that might be done on these specimens may include tests for HIV, other viruses, or immune function tests (ability to fight infection). We will not test for genetic problems or use the specimens for cloning or commercial purposes. You may choose not to have your specimens stored for future research and still be part of this study.

Are you willing to have your specimens frozen for future use?

Yes
No