

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

Attachment 4a

RCT 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: 7.5*

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 sponsored by the Centers for Disease Control and Prevention (CDC).

Introduction

The study is 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. We expect to have up to 3,500 men take part in this research. If you decide to take part, the things we learn from you will help create better HIV prevention programs for our community.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.

Purpose

We are doing a 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, home-test, and read and report their results. We also want to know if men will give home-tests to others to use.

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.

If you are eligible and agree to participate, after taking a survey, some participants will be mailed HIV test kits to test themselves at home and/or to give away to others. Two rapid HIV home-tests will be used – OraQuick® and Sure Check®.

The OraQuick® In-Home HIV Test is approved by the Food and Drug Administration (FDA) for home use. It can be bought in stores or online. The version of this test that is administered by a professional has been widely used in the US.

The Sure Check® HIV 1/2 Assay is FDA approved for professional use, but not home use, and has also been widely used in testing programs in the US. Since it is not approved for home use, it is being used in this study as an investigational device under an exemption from the FDA and with permission from the Emory University Institutional Review Board. ***The use of Sure Check® in this study is for research purposes only. Anyone who uses the test accepts that they are voluntarily using it as part of a research study.***

With OraQuick®, you will swab your mouth and collect an oral fluid sample. With Sure Check®, 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

If you have problems with home-testing, concerns, or test positive, you will have access to a toll-free helpline number 24 hours a day, 7 days a week. We also have 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.

Over a 12 month period, up to 4 follow-up surveys may be sent to you to take online or using your smart phone.

Some participants will be mailed HIV test kits at the end of the study and will be asked to collect and prepare a dried blood spot specimen, and mail it back to us in a pre-paid shipping envelope. Each test and the dried blood spot collection kit will have written instructions. A video showing how to use each test can be watched online or on a smart phone. Persons who take the tests will be asked to enter their results. The dried blood spot specimen will be tested for HIV at a laboratory with different lab tests and the results will compared with the rapid HIV home test results you reported. If the lab results do not agree with one another or with the rapid HIV home test results you reported you might be asked to send another dried blood spot specimen.

. The first survey will take about 15 minutes. Testing yourself could take up to 45 minutes. Reporting results will take about 5 minutes. Each follow-up survey will take about 10 minutes. Collecting the dried blood spot specimen will take about 5 minutes, and packaging it to mail will take 2 minutes.

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, shipping address, phone number or email address through receiving a package containing HIV home-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 the HIV tests and collecting a dried blood spot specimen. Compensation or medical treatment will not be provided if injury occurs. 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 could learn your current HIV status using a free home-test. We will confirm your results from the lab testing of your dried blood spot specimen. There are no additional direct benefits, but researchers will learn about men's willingness to use rapid HIV home-tests.

Token of Appreciation

If you take part you will receive a token of appreciation up to \$80 for completing the study activities. You will receive this 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 such as the FDA 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. Your contact information will be kept for at most two (2) years after the end of the study, as per FDA regulation and then will be destroyed and will never be associated with the study data collected.

If your lab test is positive, your contact details will be reported to your state or city health department. This information remains secure and private when it is reported to the state or city 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 or city health department. This is required by law. If your rapid HIV home test result is positive or the rapid home test results and the lab test result do not agree, Emory study staff will contact you by phone, and by email or text if unsuccessful by phone. They will provide you with more information and link you to services in the city where you live. If the results of your rapid tests and your dried blood spot lab test is negative, study staff will not contact you with your dried blood spot test results.

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, shipping 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; the FDA, 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
pssulli@emory.edu

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: 1-866-728-1885.

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 consent to store samples, then go to the Eligibility Screener.

Consent to Store Samples for Future Use

We would like to freeze part of the dried blood spot 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

* Reading level does not include HIPAA Authorization language.