Title: Implementation of Rapid HIV Self-Testing among MSM Project (iSTAMP)

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Emory University
Consent to be a Research Subject

Title:
Implementation of Rapid HIV Self-Testing among MSM Project (iSTAMP)

Principal Investigator: Patrick Sullivan, Ph.D., Emory University, Rollins School of Public Health, Dept. of Epidemiology

Sponsor: Centers for Disease Control and Prevention (CDC)

Introduction
You are being asked to be in a research study led by Emory University, the University of Michigan, and the University of North Carolina. You are being asked to be in this study because you have told us that you are Black/African-American or Hispanic/Latino, human immunodeficiency virus (HIV) –negative, and are a man who has sex with other men who is over 18 years of age. We plan to enroll 3,600 men into this study. Your participation in this study will help us understand ways on how to better serve your community. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later and withdraw from the research study.**

Before making your decision:
- Please watch the video
- Please carefully read this form or have it read to you
- Please ask questions about anything that is not clear

You can print a copy of this consent form or contact the staff team to email you a copy to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form, you will not give up any legal rights.

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 any of your specific information. At most, the web site will include a summary of the results of this research. You can search this web site at any time.

What is the purpose of this study?
The purpose of this study is to compare different online recruitment approaches and HIV testing promotion strategies in supporting HIV testing for Black and Hispanic or Latino gay and bisexual men. These promotion strategies include a mobile app for a phone, and referrals to online resources. Information about sexual health and HIV testing will be provided through these testing promotion strategies. We will also ask participants to tell us about their sexual health and HIV testing history, and report HIV test results to determine whether recruitment approaches and testing promotion strategies influence HIV testing service uptake. We will also provide you helpful information about further HIV testing, counseling, prevention, and treatment.

What will I be asked to do?
If you choose to participate in this study, you will be asked to participate in a series of activities over the next four months. First, you will be asked to complete the first survey. After the survey, you will be randomly assigned to one of two groups: **group 1** gets mailed up to two home HIV self-test kits to complete; **group 2** gets mailed up to two home HIV self-test kits to complete plus access to a comprehensive mobile HIV prevention app for men called Know@Home, that

provides HIV testing reminders along with HIV prevention information, links to resources, and product ordering including STI testing, condoms, and lubricant.

You will be asked to provide the results of your home HIV test immediately after you take it using a survey link that will be emailed to you. After four months of study participation, you will complete another survey, be mailed another home HIV self-test kit and be asked to collect a dried blood spot (DBS) specimen to mail back to the study team. In the final survey, you will be asked to document any additional HIV testing you performed and to provide additional information to describe your behaviors while participating in the study. The activities are described in detail below. If you choose to return the DBS specimen, you may be mailed another blood collection kit to provide a new sample in a very small tube called a microtainer. The purpose of the microtainer collection is to evaluate the feasibility of self-collection of blood using microtainers and analyze samples for HIV infection and HIV (PrEP or ART) medications.

30-Minute Online Surveys

Within 2 weeks: If you choose to be in the study, we will ask you to complete a survey that asks questions about your sexual health, HIV testing behaviors, and background information. This survey may be split into multiple parts.

4 months: In 4 months, you will be asked to complete an online survey. The questions on this survey will be similar to the previous survey. However, there may be additional questions asked to determine whether your behaviors have changed. This survey may be split into multiple parts.

After the first four months, some participants may be asked if they would like to continue in future study activities and can then choose to participate.

Interacting with the Mail-out HIV and STI Testing Kits

If you are eligible and agree to participate, after taking a survey, you will be mailed up to three HIV self-test kits. 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 the OraQuick test that is administered by a professional has been widely used in the US.

With OraQuick®, you will swab your mouth and collect an oral fluid sample. The 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 completing the tests, you can then report your results using a secure, online survey. Testing yourself and reporting the results could take up to 30 minutes.

Product ordering also allows you to order condoms, lube, and one STI testing kit at no cost to you. The STI home testing kit screens for syphilis and oral, urethral, and rectal chlamydia and gonorrhea. Ordering these services is optional. If you do choose to order an STI testing kit, study staff will contact you to deliver results and refer you to treatment services if you test positive for an STI.

In 4 months, participants will be shipped and asked to collect and prepare a dried blood spot (DBS) 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. Collecting the dried blood spot specimen will take about 5 minutes and packaging it to mail will take 2 minutes.

The DBS specimen will be tested for HIV at a laboratory with different lab tests and the results will be compared with the rapid HIV home test results you reported.

If you choose to mail back the DBS specimen, you may then be mailed a blood microtainer collection kit after you return the DBS specimen. The collection kit will have written instructions. Collecting the microtainer specimen will take about 5 minutes and packaging it to mail will take 2 minutes.

Interacting with Video Counseling

You can choose to have an experienced HIV testing counselor help you decide whether to test using your home HIV test kit or walk you through the test over a secure video link. You have the option to talk to a counselor before using the test, while you are using the test, or after using the test. Using video conferencing software that is free to you, a trained HIV counselor will walk you through a counseling and testing session. The session will not be recorded. Before the session begins, you will be asked if you are willing to receive your test results. In this session, you will talk about how you might react to a positive HIV test. The counselor will then tell you how to conduct the test and then help you interpret and understand what the results mean for you. You will then work with an HIV counselor to develop a plan to reduce your HIV risk. The session will take about 30-45 minutes. If your test is preliminary positive, we will follow-up with you individually about where to go to do an extra test to confirm your result. If you are interested, we can help make a list of places nearby where you live where you can become linked to HIV support services such as counseling, medical advice, and antiretroviral medications. If your test is invalid, we will mail you another test kit.

Interacting with the Testing Promotion Strategy

If you are eligible and agree to participate, you may be asked to interact with a mobile application (as described above). Individuals interacting with the first app will be able to create a profile, interact with others using the website, talk to health care providers, and order home STI testing kits.

If you have problems with home-testing, concerns, or test positive, you will have access to toll-free helpline numbers in your state 24 hours a day, 7 days a week. We also have a study phone number for any concerns that you may have with the study or study staff. Both numbers are at the bottom of this form.

Documentation of HIV Testing

If you choose to be in the study and receive HIV testing, we will ask you to document your test result by providing an image of the at-home testing kit. This information will be used to evaluate changes in behaviors and health outcomes based on HIV testing promotion strategies.

HIV and STI Testing and Care-Related Information Reported to State Departments of Public Health:

If you have tested for HIV or an STI, state law may require us to report that positive test result to your local and state Department of Public Health. When your state health department gets your results, they may contact you to help with linking you to HIV care. Also, they may also help with getting your partners tested. These procedures are the same as if you were tested for HIV or another STI at a doctor's office or a clinic outside of this research study. In addition to HIV test results, it is also mandatory for laboratories to report CD4 and viral load test results to the Health Department. As part of this study, we may request your laboratory test results from the state Department of Public Health in order to confirm self-reported HIV test results and linkage to care.

Follow-Up and Re-Contact

Your participation in this study is very important to us. If you do not complete a study survey or do not respond to our contact, we will use available public and private databases to help us locate you and re-initiate contact or determine your vital status.

Will I be compensated for my time and effort?

You will get $20 for completing all parts of the baseline survey and $30 for completing all parts of the follow-up survey for your time and effort. You will get $50 total if you complete the study surveys. For documentation of HIV testing, you will receive an additional $10 (up to once). If you choose to mail back DBS specimens, you can receive an additional $10.

If you send back the DBS specimen and are selected to receive a microtainer and send it back, you will receive an additional $10. If you do not finish the study, we will compensate you for the activities you have completed. You will receive $80 in total if you complete all study surveys and document your HIV testing results, send back a DBS specimen, and send back the microtainer specimen. You may receive this token of appreciation through an electronic gift card (e.g. Amazon, Target).

Who owns my study information and samples?

If you join this study, you will be donating your samples and study information. You will not receive any additional compensation if your samples or information are used to make a new product. If you withdraw from the study, data and samples that were already collected may be still be used for this study.

What are the possible risks and discomforts?

There are minor risks associated with this study. Some of the questions in the survey are personal and may make you uncomfortable. We hope you will answer all questions to the best of your ability. If a question makes you uncomfortable, you can choose not to answer it. You may also stop participating and withdraw from the study at any time.

There may be minor discomfort and bruising from pricking your finger for the HIV or STI tests and collecting a dried blood spot specimen for HIV testing. Compensation or medical treatment will not be provided if injury occurs.

We will keep your HIV and STI test results confidential as well as your responses to the survey questions. Although we will take steps to reduce the possibility, there is a small chance that someone other than study staff might see your study information, study related emails, or the online surveys on a laptop or cell phone. This is unlikely, and we will take precautions to ensure this does not happen. More information about how we will protect your confidentiality is below.

It is possible that someone may see the study app, emails, or surveys that you use over the next four months. Because these surveys and the study app may ask for or provide information about HIV and STIs, there is a risk of breach of privacy. To prevent this, we recommend closing out of the app, locking your mobile phone, logging out of the web browser, and logging off your computer when you are not interacting with the HIV or STI resources.

When using an HIV or STI self-testing kit, you may find out you that you may have HIV or another STI. This may be upsetting to you. However, study staff will provide testing and treatment resources located in your community and can provide video counseling if requested, free of charge.

Will I learn anything new from this study?

It is possible that the study team will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to remain in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Will I benefit directly from the study?

This study is not designed to benefit you directly. However, you may benefit from participating because the HIV testing promotion strategies provide information and links to resources about HIV prevention and treatment. This study also allows you to order a HIV testing kit at no cost to you. This study may also indirectly benefit you because we may learn about how to promote prevention services that can help reduce the health burden of HIV among men who have sex with men.

Will I have to pay to participate in this study?

There will be no costs to you for participating in this study. You will not be charged for any of the research activities.

Are there other options outside this study?

If you decide not to join the study, there are HIV and STI testing and treatment referrals and supportive services available to you outside of this research. The study staff can discuss these resources with you. We will provide you with a list of places to get these services. You do not have to be in this study to get tested for HIV or other STIs or to receive assistance with getting HIV and STI treatment and supportive services.

How will you protect my private information that you collect in this study?

Certain offices and people other than the researchers may look at study records. Government agencies and Emory, North Carolina, and Michigan employees overseeing proper study conduct may look at your study records. These offices include the Office for Human Research Protections, CDC, the Emory Institutional Review Board, and the Emory Office of Research Compliance. Study funders may also look at your study records. Emory will keep any research records we create private to the extent we are required to do so by law. A study number rather than your name will be used on study records wherever possible. Your name and other facts that might identify you will not appear when we present this study or publish its results.

This research is covered by a Certificate of Confidentiality from the Centers for Disease Control and Prevention. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the Centers for Disease Control and Prevention which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law regarding reporting of communicable diseases, including HIV and other STIs. The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

If your rapid HIV home test result is positive or your STI results are positive, study staff will contact you by phone or email to offer further services, including video prevention counseling. They will provide you with more information and link you to services in the city where you live.

How will you share my information?

De-identified data from this study may be shared with the research community at large to advance science and health. Data from this study may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Can I withdraw from the study?

You have the right to leave a study at any time without penalty. The study team also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

Contact Information

If you have any questions about the study or problems with using the tests, you can contact study staff [redacted] or [redacted]

- if you have any questions about this study or your part in it,
- if you have questions, concerns or complaints about the research
- if you have any problems with the study tests

If you test positive or you would like to speak someone about the results of your test, you can call this toll-free number 24 hours a day, 7 days a week: [redacted]. You can also call the following numbers based on where you live.

- Alabama: [redacted]
- California: [redacted]
- Florida: [redacted])
- Georgia: [redacted]
- Louisiana: [redacted]
- Mississippi: [redacted]
- Nevada: [redacted]
- New York: [redacted]
- North Carolina: [redacted]
- South Carolina: [redacted]
- Texas: [redacted]

Contact the Emory Institutional Review Board at [redacted]

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

You may print a copy of this form to keep. If you would like a copy of this form, but are unable to print it, you may contact Dr. Patrick Sullivan at [redacted]

Consent and Authorization

☐ **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.**

Consent for Contact for Optional Study/Studies:

Please check the box below if you consent to be contacted for future studies conducted by Emory University. Only your contact information would be kept for this purpose. The data you provide today will not be used as a part of future Emory University studies for which you may be contacted.

☐ **I would like to be contacted for participation in future Emory University research studies.**

☐ **I would not like to be contacted for future studies.**

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. If you do not want to have your samples stored, please send an email to [redacted] "Do Not Store Sample for Future Use" in the subject line.