Form Approved

OMB No. 0920-New

Expiration Date: XX/XX/XXXX

Web-based Approaches to reach black or African American and Hispanic/Latino MSM for HIV Testing and Prevention Services

Attachment 4b

Study consent form

Study Consent

Emory University is conducting a sexual health research study among men who are 18 years or older and who have sex with men. In this study, Emory University, the University of Michigan, Emory University, and the University of North Carolina would mail out HIV home-testing kits. If you are eligible for this study, which is funded by the Centers for Disease Control and Prevention, we will invite you to help us test a program for delivering at-home HIV testing.

You will be asked to install and use an application on your smartphone. The application will provide you with information on ways to monitor and maintain your sexual health, and occasionally prompt you for feedback or information. Our goal is to assess the effect of the smartphone app on individual sexual health prevention efforts and outcomes. Participants who complete the study will be given a token of appreciation for their time and effort.

Participating in this project may involve:

- Downloading a mobile app on your personal device
- Taking online surveys
- Testing yourself for HIV and/or STIs

Are you interested in participating?"

Yes → "Please read through this 'Study Screening Consent Form'. Please let me know if you have any questions." *[proceed to Appendix C – Study Screening Consent Form]*

No → "Thank you for your time." *[terminate interaction]*

Study Consent

Study screening consent form

Emory University

Consent to be Screened for a Research Study

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 invited to take a short survey to determine your eligibility for participating in a research study at Emory University. 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.

Taking this survey does not mean you must join the study. If you are eligible and choose to join, you can still change your mind later. You can quit the study at any time.

You can print a copy of this consent form or contact the staff team to email you, 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.

Before making your decision:

- **Please watch the consent video**
- **Please carefully read this form or have it read to you**
- **Please ask questions about anything that is not clear**

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.

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 men who have sex with other men (MSM) in the US. These promotion strategies include a sexual health mobile app, sexual health website, 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 have an effect on HIV testing service uptake.

What will I be asked to do?

If you agree to take this survey to see if you are eligible for the study, you will take an Internet survey that will take about five minutes. All of your answers to the survey questions will be private.

Study Consent

In this survey, you will be asked questions about the following topics:

a) **Your age, race/ethnicity, and gender**

b) **Your sexual behavior**

c) **Your HIV testing history**

d) **Your current HIV status**

e) **Your contact information**

You will take this survey on a computer or on a mobile phone. The website where the survey is located is secure and any answers you give us will be safely stored on a password-protected computer. Researchers will not be able to link your responses to you or your Facebook or Google page. You can refuse to answer a question at any time. If you don't answer a question, or if you want to end the survey, there will be no penalty for you. If you decide not to continue with the survey at any point in time, you can close the window to exit the survey.

Based on your responses to this survey, you may be asked to participate in a research study. If you are asked and agree to participate in the study, we will ask that you provide additional information, including contact information. If you are not eligible for the study, you will be asked if you would like to leave your contact information so that you can be contacted for future studies for which you might be eligible.

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.

All of your answers will remain private. Some of the questions in the survey are about sex and may make you feel uncomfortable. Your participation is completely voluntary and you can refuse to answer a question at any time.

If you are preliminarily eligible for the study and interested in moving forward with the screening process, we will collect your phone number, email address, and first name so that we can contact you with further instructions for the study. This information will only be viewed by study staff.

Will I benefit directly from the study?

There are no direct benefits by taking this survey. The information from this Internet survey may be used to determine eligibility for a research study.

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.

Will I be compensated for my time and effort?

If you agree to take this survey, you will not receive any tokens of appreciation (money or otherwise) for taking this survey. However, if you pass this screening and choose to enroll in the research study, you will be eligible to receive up to $70 if you complete the survey and laboratory testing activities.

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 point to 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.

The contact information you give us will be kept in a secure location. If you are eligible to participate, this information will be used to contact you to provide more information about the research study and then will be destroyed after the end of the study. The survey answers you give us will be grouped with survey answers from other persons. Researchers will not be able to link your responses to you or your Facebook page. If you are asked and agree to participate in the research study, you will be asked to provide additional information. You do not have to participate in the study and you can still participate in this survey even if you do not want to provide additional information for the research study.

Can I withdraw from the study?

Being in this research is voluntary and you have the right to refuse to answer all questions in the survey. You can stop at any time after giving your consent 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

Contact study staff at 404-727-4340 or iSTAMP@emory.edu:

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

Contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu:

- **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 pssulli@emory.edu or study staff at iSTAMP@emory.edu.

Consent and Authorization

☐ **I am at least 18 years of age, agree to the above information and would like to volunteer for this research.**

☐ **I would not like to volunteer for this research.**

If you do not want to volunteer for this survey, you may simply close this window.

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.**

- *[**If "No,"** participant is directed to a webpage reading:]*

  "You have indicated that you do not consent to taking the eligibility screener for our study. We require all respondents to consent to take the eligibility survey in order to participate in the study, so we cannot allow you to participate. Thank you for your interest in our study.

  For information about HIV/AIDS, where you can find HIV testing, prevention and sexual health services, please visit AIDSVu.org."

- *[**If "Yes,"** participant is directed to a screener webform (Appendix D)]*

Thank you for your interest in this health study. Unfortunately, you were not selected to participate any further.

If you are currently HIV-negative, pre-exposure prophylaxis (PrEP) may be a potential option for you. PrEP is a way for people who do not have HIV to lower their risk of getting HIV by taking a pill every day. To learn more, please visit some of the links below.

If you want to learn more about HIV, where to get more information, or where to get tested in your area, please click on the following links:

- Information about HIV
  - www.cdc.gov/hiv
- HIV Testing Resources
  - CDC HIV Testing Locator (https://gettested.cdc.gov/)
  - CDC HIV Testing Information Page (https://www.cdc.gov/hiv/testing/)
  - HIV.gov HIV Testing Locator (https://www.hiv.gov/locator)
  - AIDSvu HIV Testing Locator (https://aidsvu.org/services)
- PrEP Resources
  - Centers for Disease Control PrEP Resources (https://www.cdc.gov/actagainstaids/campaigns/starttalking/materials/prepresources.html)
  - Centers for Disease Control PrEP Information (https://www.cdc.gov/hiv/risk/prep/index.html)
  - The Fenway Institute: What is PrEP? (http://thefenwayinstitute.org/prepinfo/)
  - PrEP Locator (https://preplocator.org/)
  - HIV.gov PrEP Information Page (https://www.hiv.gov/hiv-basics/hiv-prevention/using-hiv-medication-to-reduce-risk/pre-exposure-prophylaxis)

If you have any questions or comments, you may contact study staff at iSTAMP@emory.edu or (404) 727-4340, or the Principal Investigator, Dr. Patrick Sullivan of Emory University, at (404) 727-2038 or pssulli@emory.edu. To get more information about HIV, please visit: www.cdc.gov/hiv.

Otherwise, you can close your browser window. Thank you for your time.

End survey.

End 2. If the participant is eligible:

ACTION: Webhook pushes survey completion/results to SMART

Congratulations! You are eligible to participate in this health study.

Please click on the following link to complete the registration process and enroll into this study: **[*link to registration survey*]**. Thank you for your time.

Continue to registration.

*If participant is **eligible** based on screener, participant will proceed to Appendix E – Contact Information Collection Form]*

Study Consent