Mobile Messaging Intervention to Present New HIV Prevention Options for Men who have Sex with Men: Randomized Controlled Trial

5. Consent Form

Emory University

Consent to be a Research Subject / HIPAA Authorization

Title: Mobile Messaging Intervention to Present New HIV Prevention Options for MSM

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

Introduction

You are being asked to be in a research study. 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 on and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:

- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, 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.

What is the purpose of this study?

The purpose of this study is to test a smartphone app designed to deliver sexual health messages to men who have sex with men. We will ask participants to tell us about their thoughts on the app and its use. We will also ask participants about their sexual health and history, in order to determine whether using the app has an effect on sexual health outcomes.

What will I be asked to do?

If you choose to be in this study, we will ask you to participate in a series of activities over the course of nine months. These activities will include filling out surveys about your sexual health and behavior, and interacting with a smartphone app. The study activities are described individually below:

One 90-minute baseline survey (to be completed **today** by consenting individuals)

If you choose to be in this study, we will ask you to complete a survey to establish some basic facts about you for our study, such as your sexual history, medical history, behaviors and attitudes.

Three 90-minute follow-up surveys (to be completed in 3 months, 6 months, and 9 months from today by consenting individuals)

If you choose to be in this study, we will ask you to complete a series of follow-up surveys for our study. Our follow-up surveys will repeat questions asked in the baseline survey to determine whether your behaviors, beliefs and attitudes have changed.

App Interactions

We will randomly choose half of consenting participants to get access to the smartphone app today. Participants will be expected to regularly interact with the app for a total of 3 hours over the course of 3 months, or an average of 2 minutes per day during the app use period. As you use the app, it will collect data about that use.

Participants who do not get the app today will get access to the app in approximately 9 months, if they wish to access the app. Participants who request access to the app in 9 months will be asked if they wish to complete additional follow-up surveys.

5-minute update surveys (to be completed as needed, if life changes occur)

The smartphone app designed for this study selects sexual health and prevention messages to deliver to you based on the information you provide to us through our surveys. The participants will be prompted to answer a 1-minute survey of message tailoring questions upon logging into the app for the first time, and will be prompted to update their responses after 1 and 2 months of app use. The participant's responses automatically determine which subset of messages are delivered to app users. This tailored messaging will take place automatically as participants provide new data.

Who owns my study information and samples?

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

What are the possible risks and discomforts?

We believe this study poses minimal risk to you as a participant. You may feel nervous, shy or feel discomfort talking about sex acts and beliefs. You do not have to answer questions that you do not wish to answer.

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. Doing this research study may not benefit you personally. We may learn about how to promote prevention services that can help reduce the health burden of HIV among MSM.

Will I receive a token of appreciation?

You will get a token of appreciation for each completed study visit. Upon completing the 90-minute baseline survey, participants will receive a $50 token of appreciation. You will also be asked to return to this study site at the end of the study to complete a final follow-up survey, for which participants will receive a $50 token of appreciation. Participants will be asked to complete two 90-minute follow-up surveys online, and will receive a $20 token of appreciation for each survey.

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

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results. The file linking your name to your study number will be securely housed by Emory University, inaccessible to study staff except as needed for routine study procedures. Study records can be opened by court order. They also may be provided in response to a subpoena or a request for the production of documents.

Storing and Sharing your Information

The data you provide will be stored securely, with all names and data that could be used to identify you removed. The data you provide are to be used only by study staff. Your contact details will be stored securely, for use only when contacting you for study activities described in this form. The data you provide will not be used for other research.

Costs

There will be no costs to you for being a part of this study, other than basic costs like travel. You will not be charged for any of the research activities.

Withdrawal from the Study

You have the right to leave a study at any time without penalty. The study team also have the right to remove you from in this study without your consent for any reason. The study team may remove you from the study 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.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for the study.

PHI that Will Be Used/Disclosed:

The PHI that we will use or share for the main research study is your HIV status.

Purposes for Which Your PHI Will Be Used/Disclosed:

We will use and share your PHI for the conduct and oversight of the research study. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your or contact information.

Use and Disclosure of Your Information That is Required by Law:

We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests or orders that require us to disclose your PHI. These include subpoenas or court orders.

Authorization to Use PHI is Required to Participate:

By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form to authorize the use and disclosure of your PHI. If you do not sign this form, then you may not participate in the research study.

People Who Will Use/Disclose Your PHI:

The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study.
- Emory may use and disclose your PHI to run normal business operations.
- The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.

- Centers for Disease Control and Prevention is the supporter of the study. The supporter will not have access to your PHI. Study staff will not disclose PHI to CDC team members.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory, University of Michigan and Public Health Solutions offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Government agencies that regulate the research including: Office for Human Research Protections.
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your PHI may be shared with that new institution and their oversight offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

Expiration of Your Authorization

Your PHI will be used until this research study ends.

Revoking Your Authorization

If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact the study team at:

ATTN: MMI4MSM Team. 1518 Clifton Road NE, GCR 446, Atlanta, GA 30322

At that point, the study team would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data is correct. If you revoke your authorization you will not be able to stay in the study.

Other Items You Should Know about Your Privacy

Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to

follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them.

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information

Contact study coordinator Ryan Zahn at 404-712-0123 or principal investigator Patrick Sullivan at 404-727-2038:

- 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.

Consent and Authorization

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.

- **Checking this box indicates your consent to be contacted for participation in future Emory University studies.**

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in the main study. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the form to keep.

_____

Name of Subject

_____ _____

Signature of Subject (18 or older and able to consent) **Date** **Time**

TO BE FILLED OUT BY STUDY TEAM ONLY

_____

Name of Person Conducting Informed Consent Discussion

_____ _____

Signature of Person Conducting Informed Consent Discussion **Date** **Time**