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

Fleish-Kincaid Reading Level: 8.8

<u>Title</u>: Web-based HIV behavioral trend analysis among MSM

Principal Investigator: Patrick Sullivan, PhD DVM

Funding Source(s): Emory University, Centers for Disease Control and Prevention (CDC), Manila Consulting Group, Inc.

Introduction

You are being asked to be in a study that will be led by Emory University's Rollins School of Public Health. The study is an online survey. This survey will attempt to learn more about the health of men who have sex with men (MSM). The survey is designed for all men who have sex with men. Up to 170,000 men in the U.S. will take this survey annually over the next three years. The survey data will help researchers improve HIV prevention.

Purpose

The study aims to find out about the use of technology, interest in and understanding of different HIV prevention methods, as well as general health and sex health among MSM.

Procedures

If you agree to be in this study, this is what will happen.

- **1.** You will first be screened to see if you qualify to be in the study.
- **2.** If you qualify, you will be given the opportunity to complete the survey.

The survey has questions about your health, drug use, sex practices, and HIV prevention services. It will take about 15 minutes.

This survey is confidential. We will not ask your name. We will ask for your county of residence, city of residence, zip code and researchers will have access to your IP address. The survey asks personal things. They may be hard to talk about. You may refuse to answer any questions at any time for any reason. If you refuse to answer a question you will not be punished in any way.

Risks and Discomforts

There are no major risks with being in this study. You may feel uncertain when answering some sensitive questions, but you always have the right to skip a question that you do not want to answer.

Benefits

This study is not designed to benefit you directly. This study is designed to learn more about general health and preferences among MSM. Taking part in this research study may not benefit

you. But, we may learn new things from this research that will help us improve the health of MSM.

Compensation

You will not be paid for being in this study.

Confidentiality

What you tell us is confidential *except as otherwise required by law*. Study staff at the Rollins School of Public Health at Emory University, CDC and Manila Consulting Group, Inc. can see study data. Agencies that oversee research will also have the right to look at the study data. We will group all the data from all surveys together. Only grouped data will be reported. Your identifying IP address will be kept in a secure location and will be destroyed soon after all of the surveys are collected for this round of the project.

The survey is set so that people cannot see the survey that was completed at that computer once finished. *Computers with study data will be locked and protected by passwords*. Only specific study staff will have access to the locked file cabinet or the *computers*.

There is a Certificate of Confidentiality for this Study:

What the Certificate of Confidentiality protects:

The Centers for Disease Control and Prevention has given this study a Certificate of Confidentiality. Emory would use it to block a legal request to give out study information. For example, if Emory received a subpoena for study records, we would say no. The Certificate gives Emory legal backup to say no. It covers information about you that could harm your image or finances. It also covers information about you that could harm your chances at a job or getting insurance.

What the Certificate of Confidentiality does not protect:

The Certificate would not protect some information about you, including any information:

- you give out yourself
- someone other than you or Emory gives out
- that Emory must give to state public health offices about certain infectious diseases
- that Emory must give to law officials if child abuse has taken place
- that Emory must give to prevent immediate harm to you or others
- that Emory needs to give to the study funder

Authorization to Use and Disclose Health Information

If you agree with this document and take part in this study, you are allowing the study staff at Emory University to use or release health information from the survey about you for this study. The health information that may be used or released for this study includes all information collected during this study. Although we do not collect your name, certain information may identify you to certain people. The people who may receive your information may include, but are not limited to, individuals involved in the study at Emory University, the CDC and Manila Consulting Group, Inc. In addition, people and committees at Emory will have access to your health information to provide oversight for the study. We will use your health information to conduct the study and to find research results. Health information is used to report results of the study. It may also be reviewed to make sure we are following rules, policies and study plans.

Emory University is required by the HIPAA Privacy Rule to protect your health information. By agreeing with this document and taking part in this project, you are allowing Emory University to use and/or release your health information for this study. Those persons outside of the Emory University study staff who receive your health information may not be held in compliance by the HIPAA Privacy Rule but are required to protect it under other Federal and/or state laws in sharing and using the information with others.

You may change your mind and take back this Authorization at any time, except to the extent that Emory University has already acted based on this Authorization. To take back this Authorization, you must write to Dr. Patrick Sullivan, Emory University, RSPH, 1520 Clifton Road, Atlanta, GA 30322. If you take back this Authorization, you may no longer be allowed to participate in this study. Furthermore, even if you take back this Authorization, the researchers may still use and disclose health information they already have collected as necessary. Your protected health information is being kept as part of a database and, therefore, this Authorization will expire at the end of the research study.

Costs

You will not be charged any costs for participating in this study.

Withdrawal from the Study

Doing this interview is VOLUNTARY. You are not giving up any legal claims or rights for being a part of this study. You have the right to not answer any questions. You can stop the survey at any time you want.

Questions

If you have questions contact:

- Patrick S. Sullivan, DVM, PhD, Principal Investigator at 404-727-2038
- Emory University Institutional Review Board at 404-712-0720 or toll free at 1-877-503-9797 or irb@emory.edu, for questions about being in a research study

If you want one, you may print a copy of this form to keep.

Voluntary Participation and Withdrawal from the Study

Your choice to be in this study is up to you. You have the right to not be in this study. You also have the right to stop the survey at any time. Your decision to be in or leave the study will not affect your online accounts in any way. The research team can stop you from being in this study without your consent if they believe it is in your best interest, or for any other reason.

Contact Persons

If you have any questions about the study, please contact the investigator in charge, Dr. Patrick Sullivan, at (404) 727-2038; pssulli@emory.edu.

If you have questions about your rights or you feel you have been harmed by being in this study, you may contact the Emory Institutional Review Board at (404) 712-0720 or (877)503-9797 or irb@emory.edu.

Consent

Being in this study is entirely your choice. You have the right to refuse to participate or to stop taking the survey at any time. Please print a copy of this form for your records.

If you agree to the above information and would like to be in the study, please click on the "I Agree" box below.

I agree	
☐☐☐☐I have read the information above.	I agree to participate in this study.

To print a copy of this consent form for your records, please click here