Columbia University Consent Form

Protocol Information

Attached to Protocol: IRB-AAAS3536
Principal Investigator: Lauren Chernick (lc2243)
IRB Protocol Title: Mobile Augmented Screening Tool to Increase Adolescent Testing and Linkage to Care

General Information

Consent Number: CF-AABR0720
Participation Duration: 12 weeks
Anticipated Number of Subjects: 350
Research Purpose: The purpose of this study is to understand if testing for Human Immunodeficiency Virus (HIV) can be affected by how testing is explained.

Contacts

Contact	Title	Contact Information
Lauren Chernick	Principal Investigator	Phone: 212-305-9825 Email: lc2243@columbia.edu

Information on Research

Introduction

The purpose of this form is to give you information to help you decide if you want to take part in a research study. This consent form includes information about:
- why the study is being done;
- the things that you will be asked to do if you are in the study;
- any known risks involved;
- any potential benefit;
- options, other than taking part in this study, that you have.

A trained researcher will discuss the study with you. If at any time you have questions about the study, please ask a member of the study team. Take all the time you need to decide whether you want to take part in this research study.

What information is on this form?

We are asking you to take part in a research study. This form explains why we are doing this study and what you will be asked to do if you choose to be in this study. It also describes the way we (Researchers) would like to use and share information about you. Please take the time to read this form. You should ask us any questions you have about this form and about this research study. You do not have to participate if you don't want to.

Why is this study being done?

HIV is a serious and dangerous viral infection. We are doing this research study to find out if how medical providers explain HIV testing affects the decision to be tested for HIV. We will enroll 350 participants.

What will I be asked to do if I choose to be in this study?

If you agree to be in this study, you will be explained why HIV testing is important in 1 of 2 ways-- by video or by paper. After this explanation, we will ask you if you plan to be tested. A certain group will have a choice to receive text messages over 12 weeks giving you educational information about ways to prevent HIV and other sexually transmitted infections. Some of the texts (3 out of 12) will contain links to a secure online survey asking you about substance use and sexual risk behaviors. If you click on these links, you will receive a $25 Amazon.com gift card for each survey you complete. If you complete all three surveys, you will receive gift cards worth $75.

Today, we will collect some information about you, including information about your demographics, prior use of medical care, substance use, and sexual behaviors. For some participants, we will collect your phone number to send the text messages and email address to contact you in case your phone gets disconnected. This process takes 15 minutes or less. Medical records will be accessed. We will also write down you medical record number to tally HIV results from all participants. Your HIV status will NOT be connected to your name.

Risks

Confidentiality

A risk of taking part in this study is the possibility of a loss of confidentiality. Loss of confidentiality includes having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. We will do everything we can to keep your data secure, however, complete confidentiality cannot be promised. Despite all of our efforts, unanticipated problems such as a stolen computer may occur, although it is highly unlikely. An additional risk is that some participants may have emotional reactions to questions about substance use or sexual risk behaviors asked by computer here in the emergency department, or later via text message.

A description of this clinical trial will be available on www.clinicaltrials.gov as required by US Law. The website will not include information that can identify you. At most the website will include a summary of results. You can search this website at any time.

Benefits

Are there benefits to taking part in this study?

You may receive personal (direct) benefit from taking part in this study. The possible benefits of taking part in this

study include learning about different ways to prevent HIV infection.

Alternative Procedures

What other options are there?

You may choose not to take part in this research study. Whether or not you are a part of this study will not affect the medical care you receive today.

Confidentiality

What about confidentiality?

Access to your health information is required to be part of this study. If you choose to take part in this study, you are giving us the authorization (i.e. your permission) to use the protected health information and information collected during the research that can identify you. Any research information that is shared with people outside of Columbia University Medical Center and NewYork-Presbyterian Hospital will not include your name, address, or any other direct identifier unless disclosure of the information is required by law or you have authorized the disclosure. Your phone number will be shared with a secure company who will send you text messages, who has committed to keep your number confidential.

Your information will be assigned a code number, and separated from your name or any other information that could identify you. The research file that links your name to the code number will be kept in a locked file cabinet and only the investigator and authorized study staff will have access to the file. The following individuals and/or agencies will be able to look at, copy, use, and share your research information:

- The investigator, Columbia University Medical Center and NewYork-Presbyterian Hospital study staff and other medical professionals who may be evaluating the study
- Authorities from Columbia University, including the Institutional Review Board ('IRB')
- The Office of Human Research Protections ('OHRP')
- The National Institute of Health (NIH)
- Our data and safety monitoring board
-The Federal and Drug Administration (FDA)

Your authorization to use and share your health information will expire when the research is completed. Once your health information has been disclosed to a third party (for example, a digital company who sends the text messages), federal privacy laws may no longer protect it from further disclosure. You may change your mind and revoke (take back) this consent and authorization at any time and for any reason. To revoke this consent and authorization, you must contact the site Principal Investigator, Dr. Lauren Chernick. However, if you revoke your consent and authorization, you will not be allowed to continue taking part in the Research. Also, even if you revoke this consent and authorization, the Researchers and the Sponsor (if applicable) may continue to use and disclose the information they have already collected.

Voluntary Participation

Do I have to be in the study?

Taking part in this study is voluntary and your choice. You can decide not to take part in or stop being in the study at any time. Your choice will not affect the treatment you receive from doctors and staff at Columbia University Medical Center and NewYork-Presbyterian Hospital.

Additional Information

Whom may I call if I have questions?

You may call Dr. Lauren Chernick by telephone (212) 305-9825 or email lc2243@columbia.edu if you have any questions or concerns about this research study.If you have any questions about your rights as a research participant, or if you have a concern about this study, you may contact the office below.

Human Research Protection Office
Institutional Review Board
Columbia University Medical Center
154 Haven Avenue, 1st Floor
New York, NY 10032
Telephone: (212) 305-5883
Email: irboffice@columbia.edu

An Institutional Review Board is a committee organized to protect the rights and welfare of human subjects involved in research. More information about taking part in a research study can be found on the Columbia University IRB website at: http://www.cumc.columbia.edu/dept/irb.

Statement of Consent

Statement of Consent and HIPAA Authorization

I have read this consent form and HIPAA authorization. The research study has been explained to me. I agree to be in the research study described above. A signed copy of this consent form will be offered to me. By agreeing to this study, I have not given up any of the legal rights that I would have if I were not a participant in the study.

This consent form is written to address a research subject. If, however, you will be providing permission the parent or legal guardian of a minor, the words 'you' and 'your' should be read as 'your child'.

Signatures

Participant Signature Lines

Study Subject

Print Name _____ Signature _____

Date _____

Parent/Guardian

Print Name _____ Signature _____

Date _____

Research Signature Lines

Person Obtaining Consent

Print Name _____ Signature _____

Date _____