Columbia University

Consent and HIPAA Authorization Form

Protocol Information

TITLE: mChoice: Improving PrEP Uptake and Adherence among Minority MSM through Tailored Provider Training and Adherence Assistance in Two High Priority Settings

PROTOCOL NO.: AAAT8812

SPONSOR: Centers for Disease Control (CDC)

INVESTIGATOR: Rebecca Schnall, PhD, MPH, RN-BC, FAAN

560 West 168th Street

New York, New York

10032 United States

STUDY-RELATED PHONE NUMBERS: (212) 342-6886 or (212) 305-8198

General Information

Participation Duration: 1 hour
Anticipated Number of Subjects: 30
Concise Summary:

- The purposes of this study are to 1) implement evidence-based education and support tools in clinics in order to improve the overall pre-exposure prophylaxis (PrEP) experience for providers and gay, bisexual, and other men who have sex with men (MSM); and 2) increase our understanding of factors that influence the PrEP choices.
- What is involved in this Study Aim? 1) An in-depth interview about your participation in the mChoice intervention study period.
- The time frame for your involvement is approximately 1 hour.
- Risks for the study include the potential risk for loss of confidentiality. There may be other risks of taking part in this research study that we don't know about. If we learn about other risks, we will let you know what they are so that you can decide whether or not you want to continue to be in the study. Detailed information of all the known risks can be found in the Risks section.
- There may be no direct benefits for participants in the study.
- It is your choice if you want to be in this study. The alternative is to not participate. If you decide to take part in the study, it should be because you really want to volunteer. You can choose to withdraw at any time during the study. If you choose not to volunteer, you will not lose any services, benefits or rights you would normally have.

Contacts

Contact	Title	Contact Information
Rebecca Schnall	Principal Investigator, Columbia University	Phone: (212) 342-6886 or (212) 305-8198 Email: rb897@cumc.columbia.edu

Detailed 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 and HIPAA authorization 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; and
- The way your health information will be used and shared for research purposes.

The study staff 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.

The purpose of this research is described below in the 'What is Involved in This Study?' section of this consent and HIPAA authorization form.

This consent and HIPAA authorization form is written to address a research subject.

What is involved in this study?

The purposes of this study are to 1) implement evidence-based education and support tools in clinics in order to improve the overall pre-exposure prophylaxis (PrEP) experience for providers and gay, bisexual, and other men who have sex with men (MSM); and 2) increase our understanding of factors that influence the PrEP choices.

If you agree to be in this study, the following will happen:

- You will participate in an approximately 1-hour long interview so that we can hear about your experience with PrEP, the reasons for your PrEP choice, and your impression of the mChoice intervention period.

Risks

General risks

There may be risks or discomforts in participating in this study. You may feel uncomfortable about some of the HIV prevention/PrEP-related questions during the interview. You may ask to skip questions that make you feel uncomfortable or stop the research procedures at any time.

Loss of 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. The study team plans to protect your confidentiality. Their plans for keeping your information private are described in the Confidentiality section of this consent and HIPAA authorization form.

Benefits

There are no direct benefits to you as a study participant. Your participation will assist the study in improving the overall PrEP experience of providers and MSM patients and increase our understanding of factors that influence the choice of PrEP regimen.

Alternative Procedures

The alternative is to not participate. You are free to refuse to participate or to withdraw from this research at any time. You can still get all your usual clinical care and can obtain PrEP from your usual provider outside of this study.

Confidentiality

What about Confidentiality?

Any information collected during this study that can identify you by name will be kept confidential. We will do everything we can to keep your data secure, however, complete confidentiality cannot be promised. Additionally, your individual-level data will not be shared through unrestricted- or controlled-access repositories. Despite all our efforts, unanticipated problems such as a stolen computer may occur, although it is highly unlikely.

Access to your health information is required to be a 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. The health information that we may collect and use for this research may include medical history that may be considered sensitive. The health information that may be collected, used, or disclosed includes:

- All health information collected during the research described in this consent and authorization;
- Health information in your medical and pharmacy records that is relevant to the research. This may include medical information that may be considered sensitive, including HIV/STI testing, HIV status, history of drug use or alcohol abuse, pharmacy re-fills, and mental health information. Information about you may be obtained from any pharmacy, hospital, doctor, and any other health care provider involved in your care that is needed for this research purpose. Any research information that is shared with people outside of Columbia University Medical Center and New

York-Presbyterian Hospital will not include your name, address, telephone number, or any other direct identifiers unless disclosure of the information is required by law, or you have authorized the disclosure.

Once your health information has been disclosed to a third party, federal privacy laws may no longer protect it from further disclosure.

Your audio recordings 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, an encrypted data file, and/or a password-protected database and only the investigator and authorized study staff will have access to the file. The technical platform is designed to be a safe and secure environment as much as possible, for data input, data sharing, synthesis, storage, and retrieval. Your participation in this research study will be documented in your electronic health record. This record can be viewed by authorized personnel from Columbia University Irving Medical Center, Weill Cornell Medical Center and New York-Presbyterian Hospital and its affiliated institutions, because these institutions share the electronic medical record system.

Identifiers might be removed from the participant's identifiable private information or biospecimens and, after such removal, the information or biospecimens could be used for future research studies or given to another investigator for future research studies, without asking for additional informed consent. If information from this study is published or presented at scientific meetings, your name and other personal information about you will not be used.

The following individuals and/or agencies will be able to look at, copy, use, and share your research and health information:

- The investigator, Columbia University Medical Center, New York-Presbyterian Hospital, and the 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')
- Our sponsor of this study, Centers for Disease Control ('CDC');
- Food and Drug Administration (FDA).

Certificate of Confidentiality

This research project has a Certificate of Confidentiality from the Centers for Disease Control and Prevention (CDC). Unless you give permission, researchers cannot release information that may identify you for a legal action, a lawsuit, or as evidence. This protection applies to requests from federal, state, or local civil, criminal, administrative, legislative, or other proceedings. As an example, the Certificate would protect your information from a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT protect your information if a federal, state or local law says it must be reported. For example, some laws require reporting of abuse, communicable diseases, and threats of harm to yourself or others. The Certificate CANNOT BE USED to stop a federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop reporting required by the U.S. Food and Drug Administration (FDA). The Certificate also DOES NOT stop your information from being used for other research if allowed by federal regulations.

Researchers may release your information when you say it is okay. For example, you may give them permission to release information to insurers, your doctors, or any other person not connected with the research. The Certificate of Confidentiality does not stop you from releasing your own information. It also does not stop you from getting copies of your own information.

Recordings

We are asking for your permission to allow us to audiotape your voice as part of the in-depth interviews in this research. The recordings will only be used for analysis by the research team. The recording(s) will include your words. The audio recording(s) will be stored on a password-protected computer in a locked office in the Columbia University School of Nursing and will be destroyed after transcription, which is to happen 2 weeks after the original recording. However, the transcriptions will remove any information that may identify you. The investigator and the study staff will have secured access to the audio recording(s). Your signature on this form grants the investigator named above permission to record you as described above during participation in the above-referenced study. The investigator will not use the recording(s) for any other reason than that/those stated in the consent and HIPAA authorization form without your written permission. The following investigators and/or agencies will be able to access your recording(s):

- The investigator, Columbia University Medical Center, New York-Presbyterian Hospital, and the 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')
- Our sponsor of this study, Centers for Disease Control ('CDC');
- Food and Drug Administration (FDA).

There is no additional incentive for allowing yourself to be taped, aside from the $25 you will be given for completing the in-depth interview (see *Tokens of Appreciation* section).

1. I give permission to record: _
2. I do NOT give permission to record: _

Participant signature granting permission to record:

_____

Revoking this Consent and HIPAA Authorization

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 Principal Investigator, Rebecca Schnall at rb897@cumc.columbia.edu or (212) 342-6886. However, if you revoke your consent and authorization, the researchers, and the sponsor (if applicable) may continue to use and disclose the information they have already collected.

Tokens of Appreciation

You will receive $25 for your participation in this in-depth interview.

Additional Costs

There are no additional costs to you for taking part in this study.

Additional Information

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Questions or Concerns about Research

If you have any questions, concerns, or complaints about the study, or if you have experienced injury or harm that may be related to the research, you may contact: Dr. Rebecca Schnall at (212) 342-6886 or (212) 305-8198 or rb897@cumc.columbia.edu.

If you have any questions about your rights as a research participant, or if you have questions, concerns, or complaints about this study, you may contact:

Human Research Protection Office,
Institutional Review Board Columbia
University Medical Center
Address: 154 Haven Avenue, 2nd 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 the consent and HIPAA authorization form and talked about this research study, including the purpose, procedures, risks, benefits, and alternatives with the researcher. Any questions I had were answered to my satisfaction. I am aware that by signing below, I am agreeing to take part in this research study and that I can stop being in the study at any time. I am not waiving (giving up) any of my legal rights by signing this consent form. I will be given a copy of this consent and HIPAA authorization form to keep for my records.

Signatures

Participant Signature Lines:

Study Participant

Print Name: _

Signature: _

Date: _