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 NUMBER(S): (212) 342-6886 or (212) 305-8198

General Information

Participation Duration: 18 months

Anticipated Number of Subjects: 400

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? 1) A baseline assessment which consists of an online survey containing questions about your background and behaviors; 2) If you choose oral PrEP, you will be given a smart pill bottle (CleverCap LITE) to use over the course of the 12-month study visit and you will be given access to the CleverCap app; 3) You will receive counseling on all PrEP choices; 4) You will be asked to participate in 3-, 6-, 9-, 12- and 18-month follow-up visits, which include follow-up assessments; 5) You will be asked to log sexual activity on the CleverCap app; 6) You may be asked to provide urine sample(s) throughout the course of the study; 7) We will collect data on your use of PrEP, switching PrEP regimens, and HIV and sexually transmitted infection (STI) test results through Electronic Health Record (EHR) and pharmacy record data; and 8) You may also be asked to participate in an in-depth interview to help us better understand how useful the app was in supporting your use of PrEP (participation in the interview is not required nor will it affect your ability to participate in mChoice).

- The time frame for your involvement in the study is 18 months.

- 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.

Throughout the study you will receive usual clinical care including counseling on your PrEP options and all recommended support and monitoring.

The study goes on for 18 months.

If you agree to be in this study, the study process includes:

- At your baseline appointment:
    - You will complete an online survey containing questions about how you identify, sexual and drug use behaviors, and other questions including attitudes, beliefs, and knowledge related to PrEP.
    - If you are using or starting with PrEP pills, you will be given a smart pill bottle (CleverCap LITE) to use over the course of 12 months. The CleverCap fits on standard pill bottles, dispenses only the prescribed amount of medication, keeps track of medications dispensed, and communicates wirelessly with mobile devices to electronically keep track of how you are taking your medication. The CleverCap LITE device is currently only used in research and has not yet been approved by the FDA.
    - You will receive access to the CleverCap app which includes 1) key information about PrEP choices; 2) videos and testimonials of young MSM; 3) two-way communication between participants and the study staff; and 4) medication and appointment reminder messages and an adherence log. The CleverCap app is currently only used in research. Study staff will help you set up the app on your phone.
    - If you report using tenofovir-containing PrEP in the last week and/or emtricitabine-containing PrEP within the past 24-hours, you will take a urine sample to measure tenofovir and/or emtricitabine levels. The point-of-care (POC) urine testing strips are currently only used in research and are not FDA approved. The results of the urine test are helpful for research into PrEP, but they will not be returned to you because they are not likely to be useful in your clinical care.

- At the 3-, 6-, 9-, and 12-month follow-up appointments, which will coincide with your clinical PrEP care visits:
    - You will complete a follow-up online survey containing questions about usefulness of the CleverCap app, sexual and drug use behaviors and other related topics including attitudes, beliefs, and knowledge related to PrEP.
    - If you report using tenofovir-containing PrEP in the last week and/or emtricitabine-containing PrEP within the past 24 hours, you will then take a urine sample to measure tenofovir and/or emtricitabine levels.
    - At the 12-month follow-up appointment, you will return the CleverCap device and the CleverCap app will be removed from your phone.
- From your first visit to your 12-month visit you will use the CleverCap app to log sexual activity.
- At the 18-month follow-up appointment:
    - You will complete a follow-up assessment which consists of an online survey containing questions about sexual and drug use behaviors and other related topics including attitudes, beliefs, and knowledge related to PrEP.

- Throughout the course of the study we will collect data on your use of PrEP, switching of PrEP regimens, and HIV STI testing results through Electronic Health Record (EHR) and pharmacy record data. If we need a separate authorization form signed by you to obtain the information from your health records, we will contact you to ask for authorization.
- You may also be asked to participate in an in-depth interview following the completion of your study visits to help us better understand how useful the app was in supporting your use of PrEP. Participation in the interview is not required nor will it affect your ability to participate in the mChoice study.

- You may also receive text messages, emails, or phone calls from the study team if you choose these methods of communication. Text messages, emails and voicemails will be vague and will not disclose participation in the study nor HIV status.

Technical Difficulties

If you have any technical difficulties using the Clevercap LITE device or the CleverCap app, please contact our study staff at: (212) 305-8198 or at sonwellness@cumc.columbia.edu.

Permission for Future Contact

The researchers may want to contact you in the future. We would contact you only once to solicit your participation in any research associated with the current or future research. Your information and/or biospecimens collected as part of this research, even if the identifiers are removed, will not be used or distributed for future research studies.

Please initial in ONE place below to show what form of permission you would like to give for future contact:

1. I ONLY give permission to be contacted in the future for information relating to this study. _____
2. I give permission to be contacted in the future for this study AND other future studies. _

Permission to Receive Reminders and Notifications

During this research, we would like to contact you for appointment reminders or for other study-related questions that we may have for you. To contact you, we may want to call you, send you text (SMS) messages and/or emails, or use your address to ship study-related materials, if necessary.

1. I give permission to be contacted by the study team (please select how you would like to be contacted if giving permission): _
   - Text
   - Phone Call
   - Email
   - Home address
2. I do NOT give permission to be contacted by the study team. _

Risks

General risks

There may be risks or discomforts in participating in this study. You may feel uncomfortable with the HIV prevention/PrEP-related information that is provided and with completing some questions in the survey. You may skip questions that make you feel uncomfortable or stop the research procedures at any time. When using the CleverCap app, it is possible that people around you may observe you using the application. If you are concerned about people seeing you use the CleverCap App, it is important that you access the application in a private location.

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.

Device Malfunction

It is possible that the CleverCap app or CleverCap LITE device may malfunction, or function incorrectly during the study period. Possible malfunctions or issues may include the CleverCap LITE device gets disconnected (typically a Bluetooth issue), the CleverCap LITE keeps dying or will not charge (battery life issue or charging cable stops working) or the CleverCap app keeps logging you out (typically due to an internet connection issue or the app is undergoing maintenance). If you run into any issues or malfunctions with any of your device(s), please contact our research team at (212) 305-8198

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 survey data, urine samples, health record data, and 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);
- UCSF Hair Analytical Laboratory (HAL);
- Abbott Rapid Diagnostics (Abbott);
- NanoComposix Laboratory.

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 for evaluation.

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.

Storage and Shipment of Urine Testing

Appropriate precautions will be employed by all study personnel in the shipment and handling of all point-of-care (POC) urine testing strips for this study, as currently recommended by institutional, state, and federal regulations that apply. POC urine testing strips will be mailed to the study site with instructions for collecting the urine and conducting the assay. The provider who is present during the visit will oversee and provide guidance for urine testing. All testing strips will be assigned an ID associated with individual participant records and shipped to the study site. We have taken steps to ensure secure handling and shipment of testing strips and protecting participant privacy while doing this, which will include but is not limited to:

- We will store the linking file containing PIDs for the testing strips will be kept in a secure electronic location and will only be accessible to study personnel.
- We will have a designated person at each site who will coordinate the shipment of packages containing testing strips, communicate delivery of packages and confirm receipt of packages with participants.
- We will have an accountability log that properly documents storage and deployment of all testing strips.
- We will properly package testing strips in high-quality packaging to avoid potential damage to the testing strips while in transit.

Assignment of Patient IDs (PIDs) will ensure test results are separated from participant names or any other information that could identify you and can only be linked using PIDs. Any information collected during this study that can identify you by name will be kept confidential. POC urine testing strips will be stored in a secure location until the completion of the research study.

Our collaborators UCSF Hair Analytical Laboratory (HAL), who helped develop this test in collaboration with Abbott Rapid Diagnostics, will provide guidance on the appropriate way to collect, analyze, and perform quality control check on the interpretation of the test results.

By signing this consent form, you are allowing UCSF, Abbott and Abbott's representatives who are involved with or are evaluating the study to access de-identified samples for processing and analysis.

Our collaborators NanoComposix who developed the Rapid Emtricitabine (FTC) test will provide guidance on the appropriate way to collect, analyze, and interpret the test results.

By signing this consent form, you are allowing NanoComposix and their representatives who are involved with or are evaluating the study to access de-identified samples for processing and analysis.

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 up to $350 after finishing the 18-month study: You will receive $40 after completing the baseline appointment, $50 after your 3-month follow-up appointment, $60 after your 6-month follow-up, $70 after your 9-month follow-up, $80 after your 12-month follow-up, and $50 after your 18-month follow-up. You will not receive any incentive for a missed appointment.

If you are asked to participate in the in-depth interview, you will receive an additional $25.

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: _