Informed Consent Form

Title: Advancing pre-exposure prophylaxis (PrEP) access in pharmacies to improve PrEP uptake in disadvantaged areas

NCT Number: NCT04393935

IRB Approval Date: April 6, 2023

Emory University
Consent to be a Research Subject

Title: Advancing pre-exposure prophylaxis (PrEP) access in pharmacies to improve PrEP uptake in disadvantaged areas" (1R34 MH119007-01)

Principal Investigator: Natalie Crawford, PhD Department of Behavioral Sciences and Health Education

Funding Source: National Institute on Mental Health

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 to consent (agree) to be in the study or not to be in 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. You can choose to not answer any question that you do not wish to answer. Your decisions will not affect your care in any way, your relationship with this pharmacy, or your relationship with Emory University.**

Before making your decision:

- Please carefully read this form or have it read 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. By signing this form, you will not give up any legal rights.

Study Overview

The purpose of this study is to determine your HIV risk.

Procedures: If you decide to participate in this study the following will happen:

1. You will be directed to a private area where you will take a twenty (20) minute survey on a tablet to determine your HIV risk.
2. After the twenty (20) minute screening you will be asked to provide your contact information. This information will only be used to follow-up with you about the study. None of your information or personal data will be shared with anyone other than yourself.
3. The pharmacist may offer you a free clinical PrEP screening following the survey. The clinical screening includes an HIV test.
4. If you are offered the clinical screening, the pharmacist or technician will provide you with a pre-packaged kit of a self-administered test for HIV to determine whether you meet biological criteria to be referred to PrEP.

   a. Video and visual instructions will be provided to you on the tablet and paper to guide you through the process of the test. You will also be able to reach an Emory staff member via phone or videoconference for questions about specimen collection.
5. Due to the sensitivity of test results, a trained pharmacy technician will interpret the clinical test results for you.
   a. If you are HIV negative, the pharmacist will offer you a 30-day PrEP prescription and an appointment to follow-up with a PrEP-prescribing physician.
   b. If you are HIV positive, a trained pharmacy technician will provide post-test counseling to you and connect you with our community partner, NAESM, who will be available to immediately link you with HIV care.

If you agree to complete the twenty (20) minute survey, you will be compensated $25 for your time regardless of your eligibility or interest in being clinically screened for PrEP. The information you provide will be used to determine whether you are eligible to receive PrEP.

Following completion of the survey, you may be offered a free clinical PrEP screening including an HIV test. You may refuse to participate at any time or if you have time constraints, you can schedule the clinical screening at a later date. If you are uncomfortable completing the screening in the pharmacy, the pharmacist or technician will also provide you with a referral to a PrEP-prescribing physician. Taking part in this pilot study is completely voluntary.

Risks and Discomforts

While we will make every effort to protect your confidentiality, there is small possibility that your confidentiality may be breached. Emory staff will protect your privacy to the extent allowed by law. No information linking your name to data collected in this study will be released or published in any form. We will make every effort to protect your confidentiality even though we cannot guarantee that a breach would never be possible.

From the twenty (20) minute survey, we will be able to automatically identify if you are behaviorally appropriate for PrEP. The pharmacist/ technician will only have information on whether you are eligible or not. They will not know the specific reason for which you are eligible.

There may also be some discomfort when answering questions about sexual behavior and drug use. You may refuse to answer any question that makes you feel uncomfortable and still complete the survey.

Benefits

This study is not designed to benefit you directly. This study is designed to learn more about your HIV risk. The study results may be used to lay the critical groundwork for understanding whether pharmacy PrEP delivery can be achieved.

Compensation

You will receive $25 for completing the screener regardless of your eligibility or interest in being clinically screened for PrEP.

Other Options Outside this Study

If you decide not to enter this study, you may access HIV prevention and treatment resources from our community partner, NAESM. We are happy to provide you with their contact information and link you directly with one of their representatives. You do not have to be in this study to receive HIV services from NAESM.

Confidentiality

Your information is protected by a Certificate of Confidentiality (CoC) which prevents anyone other than the research team from accessing your information. No offices and people other than the researchers may look at study records. Emory will keep any research records we create private to the extent we are required to do so by law. Your data will be anonymous, and your identity will be kept separate from the information you provide today. Only the study investigators will be able to link your information with your name. Your name and other facts that might point to you will not appear when we present this study or publish its results.

As protected by the CoC, your study records cannot be opened by court order. They cannot be produced in response to a subpoena or a request for production of documents.

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." Your PHI will include your HIV test results and other HIV/AIDS confidential information. To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA) and Georgia state laws on the confidentiality of HIV AIDS information. 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 for the main research study includes:

- Laboratory test results from self- administered HIV tests during this study.
- Results of exams, procedures and tests you have during this study.

Purposes for Which Your PHI Will be Used/Disclosed:

We will use and share your PHI for the conduct and oversight of this research study. We will use and share your PHI to provide you with study related treatment and for payment for such treatment. We will also use and share your PHI to conduct normal business operations. We will use and disclose your PHI for the administration and payment of any costs relating to subject injury from the study.

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

We will only use and disclose your PHI when we are required to do so by law. This includes laws that require us disclose information when medical treatment is necessary, child abuse and/or abuse of elderly or disabled adults.

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 or receive research-related treatment. You may still receive non-research related treatment.

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 and give you study-related treatments; and
- Pharmacists and technicians participating in the study at the pharmacy at Total Food and Pharmacy.

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: Natalie Crawford at [redacted]

At that point, the researchers 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. However, the research team is conducting this study in pharmacies and pharmacies are covered by the Privacy Rules, including HIPAA.

Voluntary Participation and Withdrawal from the Study
You have the right to leave a study at any time without penalty. You may refuse to participate in any procedures you do not feel comfortable with or answer any questions that you do not wish to answer.

The researchers also have the right to stop your participation in this study without your consent if:

- They believe it is in your best interest;
- You were to object to any future changes that may be made in the study plan;
- or for any other reason.

Contact Information
Contact Natalie Crawford at [redacted]

- 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 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 & Authorization

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

_____
Name of Subject

_____ _____
Signature of Subject Date Time

_____ _____
Signature of Person Conducting Informed Consent Discussion Date Time