OMB No. 0920-1423
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Expanding PrEP in Communities of Color (EPICC+)

Attachment 5b
Aim 2a Cohort Consent English

COHORT CONSENT

Florida State University
Consent to Participate in a Research Study
Participants age 18-39 years

Florida State University IRB Study # 00003652

Consent Form Version Date: Version 8.0 26-September-2024

Title of Study: Expanding Prep in Communities of Color (EPICC)
Site Principal Investigator: Lisa Hightow-Weidman, MD, MPH
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Sponsor: Florida State University (FSU)

Funding Source: Centers for Disease Control and Prevention (CDC)

Study Contact: Crissi Rainer
Study Contact telephone number: (448) 488-9069
Study Contact email: EPICC@nursing.fsu.edu

BRIEF SUMMARY

The purpose of this study is to test pre-exposure prophylaxis (PrEP) provider and patient education tools that we adapted during earlier phases of this study. Study participation involves attending a virtual study onboarding visit, your using a study app, completing surveys, collecting blood samples yourself, and allowing access to your medical record. Participation will last at least 12 months but may last up to 18 months.

The greatest risks include feeling uncomfortable when asked personal questions or others finding out information about you. While it is helpful to the study if you answer as many questions as you can, you do not have to answer any questions that you do not want to answer, and study staff will make every effort to protect your privacy. While there is no direct benefit to you for participating, the benefit of this study is the improvement of education tools that ultimately increase how many men and non-binary people of color begin taking PrEP and how often they take PrEP, thus preventing HIV within this population.

If you are interested in learning more about this study, please continue to read below.

What are some general things you should know about research studies?
You are being asked to take part in a research study called Expanding PrEP in Communities of

Color or EPICC. To join the study is voluntary. You may refuse to join, or you may withdraw your consent to be in the study at any time, for any reason, without penalty.

Research studies are designed to obtain new information. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study. You will be given a copy of this consent form. You can ask the researchers named above, or study staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?
PrEP is a once daily pill that can prevent HIV and has been studied and found to help reduce the risk of HIV. We are enrolling men and non-binary people including gender nonconforming, and genderqueer people aged 18-39 years who ever had sex (as a top or bottom, insertive or receptive) with a person who has a penis to test out educational tools, including a mobile app, that can help people start taking, and continue taking, PrEP for HIV prevention. The goal of this part of our study is to see whether these materials help men and non-binary people including gender nonconforming, and genderqueer people who ever had sex (as a top or bottom, insertive or receptive) with a person who has a penis start and continue taking PrEP.

How many people will take part in this study?
If you decide to participate, you will be one of about 400 men and non-binary people participating in this part of the study. This is part of a larger study where we expect to enroll up to 478 people.

How long will your part in this study last?
Your participation will last for at least 12 months but may last up to 18 months.

What will happen if you take part in the study?
If you choose to be in the study, you will be asked to sign this consent form electronically before you begin. You will be asked to sign a HIPAA release form so that study staff can view your medical information and collect some of your medical information to be used as research data, such as your prescription refills, lab results, and STI testing.

After you have provided your consent, you will complete a baseline survey; download and register for the mobile app; and attend a virtual study onboarding visit lasting 15-30 minutes. The study onboarding visit will provide you with an overview of the study app features, how to order a test kit in the app for the at-home blood specimen collection, and how to complete the self-collected blood specimen kit.

You will be asked to remain in the study for at least 12 months, but your participation could last up to 18 months. During this time, you will complete surveys at enrollment and every 3 months (at least 5, or up to 7, surveys in total), answer questions about how you take your PrEP medication, complete self-collected blood sample via finger prick (dried blood spot, or DBS) at enrollment and every 6 months (at least 3, or up to 4, collections in total) and allow access to your pharmacy refill and electronic medical records. The surveys will take about 30-45 minutes to complete, and you will be mailed kits to self-collect blood samples on your own. Finally, you will be asked to use the EPICC mobile app to track your PrEP use and sex behaviors, such as condom use.

A subset of participants will be invited to participate in exit interviews that last about 45 minutes.

During this interview, you may be asked questions about your PrEP use, counseling and care you received at PrEP clinics, any educational tools or other information you received that helped you make a decision about PrEP, and about your experience using the mobile app.

The blood samples you collect will be sent to a lab at the University of North Carolina-Chapel

Hill (UNC) to be analyzed for the levels of PrEP in your blood. To protect your privacy, your name will not be recorded on the samples shipped to UNC.

The study team will ask that you agree to receive text messaging and/or emails that will be automatically pushed out to your provided phone number and/or email address. Text messages and emails are unprotected forms of communication because we cannot send these messages fully secure. You can choose not to receive these unprotected messages and still participate in the study. If you agree to receive them, messages may contain personal information about you and may be sent or received by the study team's personal electronic devices or in a method that is not able to be protected with encryption and there is the risk your information could be shared beyond you and the study team. This information may include information such as reminders and notifications to contact the study team. You will be asked at the end of this consent form to indicate your choice.

If you wish to stop receiving unprotected communication from the study team or have lost your device, please tell the study team using the study contact information on the first page of this consent form. After the study is complete and all research activities finished, or you withdraw from the study or request to stop receiving unprotected communication, you will no longer receive un-encrypted (unprotected) messages specific to this study.

What are the possible benefits from being in this study?

You may not experience any direct benefit from participating in this study. The information learned from this study will assist us in developing a mobile app and other materials that can help men and non-binary people who ever had sex (as a top or bottom, insertive or receptive) with a person who has a penis make decisions about starting and continuing to take PrEP.

What are the possible risks or discomforts involved from being in this study?

You may find some of the survey questions a little embarrassing or difficult to answer. The questions are important to us, but your participation is entirely voluntary. You may choose not to answer any question or withdraw from the study at any time. If you are upset by anything we discuss, please let a research staff member know at any time.

We will make every effort to protect your confidentiality, but there is a small possibility that your name or whatever you share during the study could become known to others, for example, if someone sees the app on your phone. For this reason, we recommend turning on a password or lock feature to your main phone while you are in the study. You will have a unique password-protected login to access the app, and you will use the app with a username that does not identify you.

To protect your study data records, the data you provide will be identified with a study ID number. Your study ID number will only be linked to your name and contact information within one form in the study's secure, HIPAA compliant enrollment database. All other study records and data within the study database will only be identified with your study ID number.

Only approved research staff members can access this database using a secure server, password, and cell phone confirmation. Research staff members involved in this study are required to sign a form stating that they will protect and keep private all information on every person in the study.

The exit interviews will be digitally-recorded and converted to written text. You will be identified only by a unique study identification number, which will not identify you in any way. All written

records will be stored electronically on a password-protected computer and a paper copy will be stored in a locked file cabinet in a locked office. The audio recordings will be stored on a secure folder that only the study team can access and will be deleted after recordings are converted into written text.

The finger prick for the blood testing may be a little uncomfortable. You may also experience bruising around the site of the finger prick. In rare cases, lightheadedness and fainting may occur.

You will be informed if the study staff learns of any new risks.

How will information about you be protected?

Your participation in this study will be kept confidential and private as permitted by law. This includes the information you provide during the interview.

Your confidentiality and privacy are a high priority. All the information we collect for this research study will be kept in secure computer files. All study visits and procedures will occur in private. We will also create a unique study code for the research information we collect about you so identifying information will not remain with the data and, whenever possible, will be kept separately from your name. The results of this research may be published in a medical book or journal or be used for teaching purposes. However, your name or identifying information will not be used.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, Florida State University will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of Florida State University research sponsors, or government agencies for purposes such as quality control or safety.

At the end of the study, all of your information from the study will be coded and stored at the Florida State University in Tallahassee, FL. Samples sent to UNC, and sample results, will only be identified by their study ID number. The lab at UNC will not be able to link samples to participant names.

Identifiers might be removed from your 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 your consent again.

What is a Certificate of Confidentiality?

This research project has a Certificate of Confidentiality from the Centers for Disease Control and Prevention (CDC). Unless you say it is okay, 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.

The Certificate of Confidentiality will not be used to stop reporting as required by federal, state, or local law, such as instances of child abuse and neglect, or harm to self or others, and required communicable disease reporting.

The Certificate of Confidentiality will not be used to stop sharing your information for any purpose you have consented to in this informed consent document or in a HIPAA release form, such as research data in the medical record.

What if you want to stop before your part in the study is complete?
You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have failed to follow instructions, have undermined the right or privacy of another participant, or because the entire study has been stopped. If you withdraw or are withdrawn from this study, all data collected up until the point of withdrawal will be retained, however no additional information will be collected unless you provide additional written permission for further data collection at the time of your withdrawal.

Will you receive anything for being in this study?
You will receive the following compensation for completing each study activity listed below.

Surveys and app download:
- $50 for baseline survey and app download
- $25 for 3-month follow-up survey
- $50 for 6-month follow-up survey
- $25 for 9-month follow-up survey
- $50 for 12-month follow-up survey
- $25 for 15-month follow-up survey
- $50 for 18-month follow-up survey

In addition to completing surveys and downloading the app, you will receive an additional $50 for attending a virtual study onboarding visit.

You will receive $250 total for completing app download, 5 surveys, and onboarding visit. If you remain in the study after 12 months, you may receive an additional $75 total for completing the two additional surveys at 15 and 18months.

Returning self-collected blood specimens:
You will be asked at least three times (at baseline, 6, and 12 months after enrollment) and up to four times (18 months after enrollment) to self-collect blood specimens via finger prick (using the dried blood spot or similar method) and mail your specimen to the research team or a specified

lab. You will receive the following compensation for completing and mailing in your blood collection:

- $50 at baseline
- $50 at 6 months
- $50 at 12 months
- $50 dollar bonus for returning all 3 blood specimens: baseline, 6 months, and 12 months.
- $75 at 18 months

You will receive $200 total for returning blood specimens at three timepoints (baseline, 6-months, and 12-months), which includes a $50 bonus for returning all three blood specimens. If you remain in the study after 12 months (up to 18 months), you may receive an additional $75 total for completing the one additional blood collection at 18-months.

Exit Interviews
If you are invited to participate in an exit interview and choose to do so, you will receive $50 for completing the interview.

Total Compensation
If you complete all the above listed study activities for the 12-month study period, you will receive $500. If you remain in the study for 18 months, you could receive $650 total.

Are there any costs to you for taking part in this study?
You will not be charged for anything for taking part of this study.

Using the study mobile app may use up some of your data. Please review your data use plan to estimate what, if any, additional charges you may be billed for.

Who is sponsoring this study?
This research is being sponsored by Florida State University and funded by the Centers for Disease Control and Prevention (CDC). This means that the sponsor, the Florida State University, is receiving money from the CDC to help conduct this study. The researchers do not, however, have a direct financial interest with the funding source or in the final results of the study.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research at any time before, during, or after your participation. If you have questions, or concerns, you should contact the researchers listed on the first page of this form. If you experience injury or harm that may be related to the research please contact the study primary investigator, Lisa Hightow-Weidman by email at lhightowweidman@fsu.edu or by phone at (850) 644-3296.

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact, anonymously if you wish, Florida State Institutional Review Board (IRB) at 850-644-7900 or by email to humansubjects@fsu.edu.

FSU IRB Study #00003652

Title of Study: Expanding Prep in Communities of Color (EPICC)
Site Principal Investigator: Lisa Hightow-Weidman, MD, MPH

Participant's Agreement (for online consent)
If you select yes below to the first question, you are voluntarily agreeing to take part in this research study.

Do you agree to participate in the study?

- ❒ Yes, I agree to participate in the study.
- ❒ No, I do not agree to participate in the study.

OR

Participant's Agreement (for online consent)
I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____
Electronic Signature of Research Participant

_____
Printed Name of Research Participant

Please select the appropriate response below and provide the requested information, if applicable.

❍ Yes, I consent to the study team utilizing the following cell phone number and/or email to send unprotected communication: List your cell phone number and/or email address:

Cell phone: _____Email: _____
❍ No, I do not consent to receive unprotected communication from the study team.

You will be offered a copy of this form to keep. You are not giving up any of your rights by signing this form. Even after you have signed this form, you may change your mind at any time. Please contact the study staff if you decide to stop taking part in this study.