# PrEP2Prevent: An Online PrEP Navigation and Activation Intervention for YMSM, Trans and Non-Binary Youth (PrEP2Prevent HIV)

NCT05281393

12-6-2021

Version Date: 12/06/2021
IRB#: CHLA-20-00596

**Children's Hospital Los Angeles**
**INFORMED CONSENT/ASSENT TO PARTICIPATE IN A RESEARCH STUDY**

PrEP2Prevent: An Online PrEP Navigation and Activation Intervention for YMSM, Trans and Non-Binary Youth
(PrEP2Prevent HIV)
*Phase 3*

Subject's Name: _____

Date: _____

A person who takes part in a research study is called a research subject or participant.

## KEY INFORMATION

You are being asked to participate in a research study. This section describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide the details of the research.

### What should I know about this research?

- Taking part in this research is voluntary. Whether you take part is up to you.
- If you don't want to take part, it won't be held against you.
- You can take part and later drop out, and it won't be held against you.
- If you don't understand, ask the research team questions.
- Ask all the questions you want before you decide.

### How long will I be in this research?

Participation will last up to 6 months.

### Why is this research being done?

This research study, called **PrEP2Prevent**, is being done in several phases (parts) to develop and pilot test a PrEP activation, navigation and support intervention for young men who have sex with men (YMSM), trans youth and non-binary youth in Los Angeles. It targets an intervention for these young people where they need it most — on PrEP uptake. PrEP stands for pre-exposure prophylaxis.

### What happens to me if I agree to take part in this research?

Study procedures for Phase 3 of the study involve participating in an online or in-person enrollment visit, which will include the completion of a baseline assessment, completing 3- and 6-months follow-up visits, which include a survey assessment and urine specimen collections, and attending up to four navigation sessions with a CHLA interventionist (PrEPresentative), if assigned to the intervention arm. Participants will

also be asked to use the study mobile phone application on a daily basis for the first three months of the study period.

**Could being in this research hurt me?**
The most likely risks to you of the research are:

- The survey assessments will include some sensitive topics so you may feel uncomfortable or embarrassed sharing your answers, but you do not have to answer questions that you are not comfortable with.
- There is the potential for accidental release of confidential information.

Please see the **POTENTIAL RISKS AND DISCOMFORTS** section for a complete list of expected risks.

**Will being in this research benefit me?**
You may experience benefit from receiving a tailored, culturally-specific PrEP intervention that addresses the low rates of PrEP initiation and maintenance among YMSM, trans youth and non-binary youth, but there also may be no direct benefit to you for being in this research.

**What other choices do I have besides taking part in this research?**
You can decide not to be in the research study.

**INTRODUCTION**
You are being asked to join a research study called PrEP2Prevent led by Drs. Michele Kipke (PhD) from the Community, Health Outcomes, and Intervention Research Program at Children's Hospital Los Angeles (CHLA) and Lisa Hightow-Weidman (MD, MPH) from the Department of Medicine at the University of North Carolina (UNC). This research is paid for by the National Institutes of Health (NIH). You are invited to join this study because you are a young man who has sex with men, a person who is transgender or non-binary and you are a part of the community that is the focus of this research. Up to 150 other young men who have sex with men, trans and non-binary youth will be asked to be a part of this phase of the study. Participation in this study is completely voluntary. Please read the information below and ask questions about anything you do not understand before deciding whether or not to be in the study.

**PURPOSE OF THE STUDY**
The overall purpose of this phase of the study is to develop and pilot test a PrEP activation, navigation and support intervention for young men who have sex with men (YMSM), trans youth and non-binary youth in Los Angeles. It targets an intervention for these young people where they need it most — on PrEP uptake. It recognizes that these young people require tools and support to successfully navigate PrEP services, and uses mHealth to deliver the intervention. Moreover, the intervention can be used to both engage and re-engage these young people in PrEP uptake, and it can potentially be adapted to address uptake of long-acting PrEP and antiretroviral therapy (ART). The findings from this research will be used to engage youth who are at highest risk for HIV

and increase their knowledge about PrEP, intention to use PrEP and available services and resources, engagement in needed services, and overall PrEP uptake.

**NUMBER OF PARTICIPANTS**
150 people will be asked to take part in this phase of the study.

**LENGTH OF PARTICIPATION**
We will ask you to participate in three online or in-person visits at baseline (enrollment), 3-, and 6-months. You may also be asked to attend up to four navigation sessions with our PrEPresentative. The baseline enrollment visit will last up to 90 minutes, and will include a baseline assessment that should take about 30-45 minutes to complete. The follow-up visits at 3- and 6-months will include both a survey assessment and a urine specimen collection. The survey assessment should take 20-30 minutes to complete and the urine specimen collection should take about 15 minutes. Navigation sessions could last up to 30 minutes each. Study participation will last a total of six months.

**PROCEDURES**
If you volunteer to be in this study, we will ask you to do the following things:

- You will be asked to attend an initial in-person or online visit in which staff will describe the study, confirm eligibility, obtain informed consent, sign a HIPAA release, and complete the baseline assessment.
- The baseline assessment will ask you questions regarding demographic information, HIV/STI testing history, technology use, and other topics relate to your health and engagement with health care services. Some of the questions will involve sensitive or personal information such as questions around your health and sexuality and understanding how to prevent HIV and the importance of HIV testing and treatment. The survey will take 30-45 minutes to complete.
- Once you complete the baseline assessment, you will be randomized (randomly assigned like a flip of a coin) to the intervention application (PrEP2Prevent) or control application (standard of care). Following this, you will be guided through the application download either by study staff for in-person visits or over a video chat platform (WebEx) for online visits. You will receive help in the set-up process by study staff and the main components of the study applications will be described/demonstrated. This baseline visit will take 60-90 minutes to complete.
- You will be considered enrolled upon meeting all eligibility criteria, signing the enrollment consent/assent form, being randomized, completing the baseline survey, and successfully downloading the application on your phone.
- All participants will be asked to access and interact with the study application on a daily basis for the first three months of the study period. After the first three months, you will not have access to some features, but will still be able to use the application. You will also be asked to complete follow-up visits 3- and 6-months after the initial baseline visit. These follow-up visits will include a survey assessment that will ask questions regarding topics similar to the baseline assessment as well as questions about your experience using the study application. You will also complete urine specimen collections at these 3- and 6-months visits and will be provided with a survey link to upload your test results. This urine specimen collection will be testing for the presence of Tenofovir, an

antiviral medicine used to prevent HIV, as a biological indicator of PrEP use. You will have the option to meet virtually (via WebEx) with study staff to review the self-collection steps and to discuss the test results. Urine sample collection will involve urinating in a cup and transferring urine with a pipette from the cup to the sample tube. You will be mailed the urine testing kit and it will include detailed printed instructions regarding how to collect these samples.

- If you are assigned to the intervention arm, you will receive up to four sessions with a CHLA research staff member (PrEPresentative) over the first three months of the study period. Sessions will occur approximately one month apart, with session 1 beginning from the date of enrollment. Sessions will be scheduled via the PrEP2Prevent application and can be scheduled, based on your choice, via one of three ways: 1) text via app; 2) phone call; 3) HIPAA compliant video conferencing (WebEx) (with or without camera on). The PrEPresentative will work with you to increase self-advocacy, self-efficacy, and motivation, help you identify a pharmacy to fill prescriptions, if necessary, help you pay for prescriptions (e.g., insurance enrollment), and help develop practical, individualized behavioral strategies to support adherence. The PrEPresentative will also complete weekly check-ins with you and will be available to answer health service-related questions via text message.
- If the baseline visit and navigation sessions (intervention only) are delivered virtually via WebEx, you may be asked to create a WebEx account by research staff. Registering for a WebEx account may require you to provide personal information about yourself such as your name and email address.
- Research staff will engage with each participant, provide incentives, and be available to answer any questions about the study or its implementation.

**POSSIBLE RISKS AND DISCOMFORTS**

Some of the questions we ask you during the survey assessments will be about sensitive and personal topics such as how comfortable you are talking to your doctor about things like your sexuality, gender and sexual health, including HIV and STIs, challenges you have experienced in getting access to healthcare services like STD or HIV testing and treatment, and about your use of phone applications. These assessment topics and questions may make you feel uncomfortable, embarrassed or upset. You do not have to answer any questions that you find too sensitive or embarrassing.

The survey assessments might bring about emotional or psychological distress for you since you will be asked about sensitive topics. You might get particularly upset if the survey assessment questions or topics bring up things that you might not want to think about. If you get upset at any time, you can end survey assessment or skip the question or section causing you distress. We also have the names of people you can talk to if you would like, and if you are really upset, we will wait with you until someone can come to talk to you.

**POSSIBLE BENEFITS TO SUBJECTS**

Research is designed to benefit society by gaining knowledge. It is possible that you

may not receive any direct benefit as a result of participating in this research. However, as a result of this study, you may have the opportunity to learn about strategies to increase self-advocacy, self-efficacy, and motivation.

**POSSIBLE BENEFITS TO SOCIETY**

This portion of the study will help us develop strategies to help young men who have sex with men (YMSM), trans and non-binary youth with PrEP uptake. PrEP2Prevent is an important gender-specific and age-appropriate intervention and a much-needed tool for communities seeking to reduce the occurrence of HIV. Therefore, the study investigators believe that the possible individual and long-term community-level benefits of this study outweigh the minimal risks posed to participants.

**YOUR OPTIONS IF YOU CHOOSE NOT TO BE IN THIS STUDY**

The alternative is not to participate in this study.

**COSTS TO YOU FOR BEING IN THIS STUDY**

This research study is funded by the National Institutes of Health (NIH). Participants and their families are not responsible for any of the costs involved in this study. Neither you nor your insurance company will be billed for your participation in this research.

Using the mobile applications or completing the online surveys on your personal phone may also use part of your data plan and may cost you money. Please review your data use plan to estimate what, if any, additional charges you may be billed for.

**PAYMENT FOR PARTICIPATION**

For taking part in this research you will be paid up to a total of $280. You will be paid as follows:

You will be asked to complete three surveys, collect two urine samples, and, possibly, attend up to four sessions with the PrEPresentative. If you are selected to attend sessions with the PrEPresentative, you will be asked to complete brief satisfaction surveys after those meetings.

- You will receive $50 for completing each survey (baseline, 3- and 6-months). You will also receive $20 for completing the urine specimen collection at 3- and 6-months. If you successfully complete each assessment (baseline, 3-, and 6-months) as well as both specimen collections (at 3- and 6-months), you will receive an additional $50 bonus. If you are randomized to receive the intervention application, you will have the opportunity to complete a brief satisfaction survey after each navigation session for an additional $10 incentive ($40 total).This money will be sent to you at the end of each session via Venmo/PayPal, Cash App or Visa e-gift card. You will be sent the money even if you choose not to answer some of the questions or discuss some of the topics.

**CONFIDENTIALITY**

The survey assessment data (responses) and specimen collection results collected as part of this study will be “coded”. Coded means that the data will have your study ID recorded with them, and the link connecting the study ID to your name will be kept

separately in a secure location by a member of the research team. Only the members of the study team will be able to see the link or the information that can identify you. All of your information will be kept confidential.

Informed consents with your name will be stored at CHLA, and will only be accessible to designated research staff. Printed consent forms will be stored in a locked filing cabinet in a locked file cabinet in secure offices at CHLA.

Data files will be exported from the web-based Qualtrics platform on the server and imported into the study database for storage and analysis. Computer data files never have any identifying information, and are encrypted for transfer between study sites. Data files do not include information that could be used to identify you from the data file alone. The platform is protected with industry recognized security standards which will encrypt data and will be further protected by login credentials for limited access, to protect participant confidentiality.

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you. Your private information will be shared with individuals and organizations that oversee this research, including:

- The research sponsor, the National Institutes of Health (NIH).
- People who work with the research sponsor.
- Government agencies, such as the Department of Health and Human Services.
- The CHLA Institutional Review Board (IRB) that reviewed this research, and authorized representatives of CHLA.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health (NIH). With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and will be used for auditing or program evaluation of agency funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances:

- voluntary disclosure by researchers of information on such things as child or elder abuse, reportable communicable diseases, or possible threat to self or others.

A Certificate of Confidentiality does not represent an endorsement of the research study by the Department of Health and Human Services or the National Institutes of Health.

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity. All identifying information will be removed from audio recordings and transcriptions. Audio recordings will be destroyed once they are transcribed.

**FUTURE RESEARCH USE OF DATA**

Once this study is completed, the survey assessment data collected as part of this study will be "de-identified" or "anonymized." This means that there will be no way to link the data back to you. Once your data have been de-identified after the study has been completed, they may be used by the researcher conducting this study, the study sponsor, or other researchers (at CHLA or elsewhere) for future research projects that are related or unrelated to the purpose of this study. This future research may be done without consulting you or obtaining consent (permission) for this additional use.

**STUDY WITHDRAWAL**

The researchers may end your participation in this study for a number of reasons, such as if you do not follow instructions. The researchers or the study sponsor might also decide to stop the study at any time.

If you decide to stop being in the study, or are removed from the study, or the study is stopped, the data collected about/from you will be destroyed.

**QUESTIONS ABOUT THE STUDY**

If you have questions, concerns, or complaints about the study, or think this research has harmed you, talk to the CHLA research team.

Daytime, Monday through Friday, 8:00 A.M. through 4:30 P.M. you may call Michele Kipke, the Principal Investigator or Lindsay Slay, Senior Programs Manager, at (323) 361-3586. You may leave a message and a researcher will return your call.

During the evenings, nighttime, weekends or holidays you can leave a message on the voice mail at the same number and your call will be returned as soon as possible. If you call, please identify yourself as a participant in the PrEP2Prevent study.

*ClinicalTrials.gov* is a Web site that provides information about federally and privately supported clinical trials. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

This research is being overseen by the CHLA Institutional Review Board ("IRB"). An IRB is a group of people who perform ethical review of research studies. You may talk to them at (323) 361-2265, or hspp@chla.usc.edu if:

- You have questions, concerns or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

**RIGHTS OF RESEARCH SUBJECTS**

You can agree to take part in this study and stop your participation in the study anytime. You should not sign this form if you have any questions that have not been answered or if you are unclear about any information in this form.

Your participation in this study is entirely voluntary. If you choose to not take part in the study or decide to stop your participation in this study at any time, there will be no penalty or loss of benefits to which you are otherwise entitled. If you wish to leave the study after agreeing to participate, you should let the Principal Investigator know.

You will be told about any new information found during the course of the study that may affect your health, welfare, or choice to stay in the study. If this happens, you might be asked to sign a new consent form.

- You have a right to have all of your questions answered before deciding whether to take part.
- Your decision will not affect the medical care you receive from CHLA.
- If you decide not to take part, you can still receive medical care from CHLA.
- You will be given a copy of this signed and dated consent form to keep.
- You will be asked to sign a separate CHLA HIPAA Research Authorization form authorizing the access, use, creation, and/or disclosure of your health information.

**OPTIONAL PROCEDURES**
May the researchers contact you to invite you to participate in future research? Please provide your initials beside your decision.

_____Yes _____No

**SIGNATURE OF RESEARCH SUBJECT**

Your signature below indicates

- You have read this document and understand its meaning;
- You have had a chance to ask questions and have had these questions answered to your satisfaction;
- You consent/assent to your participation in this research study; and
- You will be given a signed copy of this form.

_____

Print Name of Subject

_____ _____

Signature of Subject Date

**SIGNATURE OF INDIVIDUAL OBTAINING CONSENT**
I have explained the research to the participant and have answered all of their questions. I believe that they understand all of the information described in this document and freely give consent/assent to participate.

_____

Print Name of Individual Obtaining Consent

_____ _____

Signature of Individual Obtaining Consent Date

**SIGNATURE OF WITNESS (if applicable)**
Your signature below indicates:

- You were present for the entire consent conference;
- The information in the consent document and any other written information was accurately explained to the subject;
- The subject had an opportunity to ask questions and those questions were answered; and
- The subject voluntarily signed the consent form in your presence.

_____

Print Name of Witness

_____ _____

Signature of Witness Date