WeExPAnd: PrEP Demonstration Project Among Women at Risk for HIV Infection - Preexposure Prophylaxis (PrEP)

Client Consent Form

NCT04373551

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Client Consent

Please read the study consent form and, if you would like to participate, sign below. Thank you!

Title of Research: We ExPAnd: PrEP Demonstration Project among Women at Risk for HIV Infection

UAB IRB Protocol #: IRB-300004276

Principal Investigator: Dr. Mirjam-Colette Kempf

Sponsor: National Institutes of Health (NIH)

General Information You are being asked to take part in a research study. This research study is voluntary, meaning you do not have to take part in it. The procedures, risks, and benefits are fully described further in the consent form.

Purpose The purpose of the study is to develop a better understanding of how to make HIV prevention medication, PrEP (known as pre-exposure prophylaxis, which is action taken to prevent diseases before it happens), more accessible to women in Alabama.

Duration & Visits You will be in this study for 3 months. Visits will include a baseline visit, intervention visit, and 3-month follow-up visit.

Overview of Procedures This study will include completing baseline assessments, watching a PrEP informational video, participating in a discussion with your provider potentially using a patient-provider communication tool, and completing 3-month follow-up assessments.

Risks The most common risk is feeling uncomfortable answering sexual health questions.

Benefits You may or may not benefit from participating in this study. However, this study may help us better understand how to optimize HIV prevention efforts and improve care in the future.

Alternatives The alternative is to not participate in this study.

Purpose of the Research Study We are asking you to take part in a research study of cis-gender women (individuals who were assigned the female sex at birth and identify as women) who are HIV-negative and potentially vulnerable to HIV. The purpose of the study is to develop a better understanding of how to make HIV prevention medication, PrEP (known as pre-exposure prophylaxis, which is action taken to prevent diseases before it happens), more accessible to women in Alabama. It is hoped that the information gained from this study will help us understand the barriers and facilitators of PrEP use. You will receive information about PrEP during this study but will not receive PrEP medication as part of this research study. We anticipate recruitment of up to 125 participants from 2 clinics.

Study Participation & Procedures If you agree to join the study:

You will be asked to participate in a baseline assessment at your baseline visit. During this visit you will be asked to provide demographic information (5-10 mins) and complete baseline assessments (20-30 mins) You will discuss PrEP with your provider using a new patient-provider communication tool (10-15 mins). This tool will be used by your provider to discuss your sexual health and to help you make informed decisions about your sexual health. You will then be asked to complete post-intervention surveys (15-20 mins). You will participate in a 3-month follow-up assessment about your health and study participation (45-50 mins). Assessments conducted at baseline and 3-months will be completed in-person on a tablet or by phone or an emailed/texted survey link. You do not have to agree to start a PrEP regiment in order to participate in this study. Data will be collected for a total of 12 months in order to have a better understanding of this study's feasibility and acceptability. Baseline and 3-month assessments will be asking you questions about HIV stigma, abuse, depression, anxiety, posttraumatic distress, substance use, religiousness, and sexual behaviors. Additionally, the 3-month assessment will include questions about your satisfaction in the study.

As mentioned, during the baseline visit, you will also be asked to complete a few demographic questions. These questions will include contact information so that the study staff can contact you regarding appointments. These questions will also include information regarding insurance coverage, annual income, and the location of your place of residence. It is important to understand exactly what this information will be used for so that you can make an informed decision to participate in this portion of the study.

We are asking you to give UAB researchers the authorization to use your address so that we can examine how you and your neighborhood influence your health and wellness. A member of the study staff will match your address to a geographic area called a census block group (CBG), which is large enough so that your exact address cannot be determined. CBG's are used by the US Census to report on demographic characteristics of entire communities. The community demographic data - and not your address- will be used by researchers to help them better understand how neighborhood and community factors relate to health and wellness. This process is called spatial mapping. Your actual address will not be reported, published, or shared with anyone else.

You can choose to opt-out of the spatial mapping portion of the study. You can still participate in the study if you choose to opt-out of this part of the study. If you choose to opt-out of this part of the study, the study staff will make a note of this in your participant file.

◯ I agree to allow spatial mapping
◯ I do not agree to allow spatial mapping

Additional Information

Your de-identified private information may be used for future research studies or distributed to another researcher for future research studies without additional informed consent.

Risks and Discomforts
- It is unlikely that you will be at risk for physical harm as a result of your study participation.
- You may find some of the questions asked in the assessments emotionally upsetting. You may decline to answer questions which upset you.

Benefits You may or may not benefit directly from taking part in this study. However, this study may help us better understand how to optimize HIV prevention efforts and improve care in the future.

Alternatives The alternative is to not participate in this study.

Confidentiality and Authorization to Use and Disclose Information for Research Purposes

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you.

All participants are assigned a study identification number. In this study, information with your name is stored separately from information that we collect for the study, which will be stored with a study identification number. The information with your name is used for tracking purposes and for contacting you or others you have given us permission to contact. Only study staff who are trained in confidentiality and research ethics are allowed access to this information.

What protected health information may be used and/or given to others?

All medical information, including but not limited to information and/or records of any diagnosis or treatment of disease or condition, which may include sexually transmitted diseases (e.g., HIV, etc.) or communicable diseases, drug/alcohol dependency, etc.; all personal identifiers, including but not limited to your name, social security number, medical record number, date of birth, dates of service, etc.; any past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of any kind, including but not limited to drug/alcohol treatment, psychiatric/psychological treatment; financial/billing information, including but not limited to copies of your medical bills; any other information related to or collected for use in the research study, regardless of whether the information was collected for research or non-research (e.g., treatment) purposes; records about any study drug you received or about study devices used; and consent forms from past studies that might be in your medical record.

A description of this clinical trial will be available on 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.

Who may use and give out this information?

Information about your health may be used and given to others by the study doctor and staff. They might see the research information during and after the study.

Who might get this information?

All individuals/entities listed in the informed consent document(s), including but not limited to, the physicians, nurses and staff and others performing services related to the research (whether at UAB or elsewhere). Your information may also be given to the sponsor of this research. "Sponsor" includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor, or are providing support to the sponsor (e.g., contract research organization).

Information about you and your health which might identify you may be given to:

The Office for Human Research Protections (OHRP) The U.S. Food and Drug Administration (FDA) Department of Health and Human Services (DHHS) agencies Governmental agencies in other countries Governmental agencies to whom certain diseases (reportable diseases) must be reported The University of Alabama at Birmingham - the physicians, nurses and staff working on the research study (whether at UAB or elsewhere); the UAB IRB and its staff The billing offices of UAB and UAB Health Systems affiliates and/or Children's of Alabama and its billing agents

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Why will this information be used and/or given to others?

Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the NIH which is funding this project 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 from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of such as child abuse and neglect, or harm to self or others.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

Information obtained during the course of the study which, in the opinion of the investigator(s), suggests that you may be at significant risk of harm to yourself or others will be reportable to a third party in the interest of protecting the rights and welfare of those at potential risk.

What if I decide not to give permission to use and give out my health information?

By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. If you refuse to give permission, you will not be able to be in this research.

May I review or copy the information obtained from me or created about me?

You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you will not be allowed to look at or copy your information until after the research is completed.

May I withdraw or revoke (cancel) my permission?

Yes, but this permission will not stop automatically. The use of your personal health information will continue until you cancel your permission.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to continue being in this study.

When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Is my health information protected after it has been given to others?

If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others, including others outside of UAB, without your permission.

Voluntary Participation and Withdrawal Whether or not you take part in this study is your choice. There will be no penalty if you decide not to be in it. If you decide not to be in the study, you will not lose any benefits you are otherwise owed.

You are free to withdraw from this study at any time. Your choice to leave the study will not affect your relationship with this institution. Contact Jimmy Winters at jwinters@fivehorizons.org, Rachel Queen at rqueen@fivehorizons.org, or Monique Petty at mpetty@fivehorizons.org if you want to withdraw from the study.

You may be removed from the study without your consent if the sponsor ends the study or if you are not following the study rules.

Cost of Participation There will be no cost to you for taking part in this study.

Payment for Participation You will be paid $100 if you complete each stage of this study: $30 baseline, $30 intervention visit, and $40 for 3-month follow-up. If you withdraw from the study you are only paid for the portions you completed. Ask the study staff about the method of payment that will be used for this study (e.g., check, cash, gift card, direct deposit).

Payment for Research-Related Injuries UAB has not provided for any payment if you are harmed as a result of taking part in this study. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge.

New Findings You will be told by the study doctor or the study staff if new information becomes available that might affect your choice to stay in the study.

Optional

Future Research Use of Identifiable Private Information and/or Identifiable Biospecimens

We would like your permission to keep your private information (data containing personal information) collected in this study for future research. The future research may be similar to this study or may be completely different. Your private information will be stored indefinitely or until used.

You can take part in this study even if you decide not to let us keep your identifiable private information for future research.

If you give us permission now to keep your identifiable private information, you can change your mind later and ask us to destroy it. However, once we have analyzed your private information, we may not be able to take it out of our future research.

We may share your identifiable private information, so that others can use it in their research. Their research may be similar to this study or may be completely different. Once we have shared your identifiable private information with other researchers, we will not be able to get it back.

Future research use of your identifiable private information will be conducted in compliance with applicable regulatory requirements.

You will not find out the results of the future research. Allowing us to do future research on your identifiable private information will not benefit you directly.

Select your choice below:

◯ I agree to allow my identifiable private information to be kept and used for future research on HIV prevention studies
◯ I do not agree to allow my identifiable private information to be kept and used for future research.

Questions If you have any questions, concerns, or complaints about the research or a research-related injury including available treatments, please contact the study doctor. You may contact Dr. Mirjam-Colette Kempf at mkempf@uab.edu or 205-934-9333

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday.

Legal Rights You are not waiving any of your legal rights by signing this consent form.

Signatures Your signature below indicates that you have read (or been read) the information provided above and agree to participate in this study. You will receive a copy of this signed consent form.

Full name of the participant _____

Signature of Participant (click "Add Signature" to sign) _____

Date Signature

_____

Name of Person Obtaining Consent

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Signature of Person Obtaining Consent

_____

Date Signature

_____