THE OPENS TRIAL OFFERING WOMEN PREP WITH EDUCATION, SHARED DECISION-MAKING, AND TRAUMA-INFORMED CARE

NCT04621760
Informed Consent Form
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Consent to Participate in a Research Study
Florida Department of Health and University of California, San Francisco

Study Title: The OPENS Trial, Aim 1

Purpose of this study: This is a research study about HIV prevention counseling. We will be testing a tablet-based tool designed to give women information about HIV prevention options. You may be asked to use the tool before your visit if you decide to participate.

About 384 people will take part in this study. You are being asked to take part in this study because you:

- Self-identified as a woman, age 18 to 45
- Are able to speak and read English
- Are not known to be living with HIV
- Are not currently using PrEP (pre-exposure prophylaxis)
- Are willing to be contacted again in 3 months via phone

Participation is voluntary. You may refuse or discontinue participation at any time with no penalty or loss of benefits to which you are otherwise entitled. Your healthcare will not be affected.

What to expect

Participation in the study will take a total of 45 minutes. If you choose to be in this study, the following will occur:

Today, before your appointment (up to 25 minutes, including the time that it takes you to enroll):

- You will be asked to complete a short survey about HIV prevention.
- You will be randomly assigned to use the tool or not, with an equal chance of being assigned to either group. The tool is designed to help women make decisions about HIV prevention.
- If you are randomly assigned to use the tool, you will use it before seeing your provider. Your provider will not know whether you used the tool or not.

Today, after your appointment (15 minutes):

- You will complete a short survey, including questions about your experience during the appointment, decisions making about HIV prevention and sexual history.

After you leave today (5 minutes):

- We will contact you in 3 months after your visit by phone, text, or email. You will be asked to complete a short follow-up survey, which includes questions about your chosen HIV prevention method.
- The research team will review your electronic medical records for your zip code, insurance status, STI diagnoses, and PrEP and PEP prescriptions. This information will be reviewed for research purposes only; we will not share your name or any personal information with anyone.

Compensation

Study participants will receive $20 gift certificate at the end of their visit today in exchange for their time and effort. Participants who complete the 3-month follow-up survey will receive another $10 gift certificate.

Benefits

There will be no direct benefit to you from participating in this study. However, the information that you provide may help health professionals better understand ways to provide information about HIV.

Potential risks or discomforts

The study surveys include questions related to sexual history and HIV which may make you uncomfortable. You can decline to answer any question that you don't wish to answer for any reason.

As part of this portion of the study, you may receive a tablet-based tool with information about HIV prevention methods. There is a risk that someone may see you using the educational tool, which could lead to embarrassment or discomfort. You can choose to decline participation in this study or stop at any time in order to avoid this risk.

Privacy

We will do our best to ensure that personal information gathered is kept private. However, we cannot guarantee total privacy and there is a potential risk that you may lose your privacy if your participation in the study becomes known. Our data is stored securely, and names or other personal identifiers will not be used if information from this study is published or presented at scientific meetings. You can choose to stop receiving texts, calls, or emails from the study you have concerns about your privacy.

Authorized representative from the following organizations may look at and/or copy your research records for research, quality assurance, and data analysis include:

- The University of California, San Francisco
- Duval County Health Department

To help us protect your privacy, this research is covered by a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you to anyone, even by a court subpoena. This does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Exceptions: A Certificate of Confidentiality does not prevent researchers from voluntarily disclosing information about you, without your consent. For example, we will voluntarily disclose information about incidents such as child abuse, and intent to hurt yourself or others. In addition, 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. Finally, the Certificate may not be used to withhold information from the federal government needed for auditing or evaluating federally funded projects or information needed by the FDA.

Contact information

If you have questions today, please ask the research assistant. You may also call Olga Goldman , the Study Coordinator at the Duval County Health Department, with any questions, concerns, or complaints about the study at 904-253-1403.

This study has been approved by an Institutional Review Board. An Institutional Review Board is a group of people who review research to ensure participants are protected and the research is conducted in an ethical way.

If you want to talk with someone independent of the research team for questions, concerns, or complaints about the research; questions about your rights; to obtain information; or to offer input, you can contact the Florida Department of Health Institutional Review Board at: 850-245-4585.

Consent

Participation in research is voluntary. You have the right to decline to be in this study, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled.

If you wish you participate in this study, please sign below. We can give you a copy of this form to keep.

Date	Participant's Signature for Consent
Date	Person Obtaining Consent