

Study Title: PrEPARE: PrEP in Pregnancy, Accelerating Reach and Efficiency

NCT#: 04712994

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Oral Consent Guide

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It is important to cover the following topics with the study participants:

Background information:

- Kenyatta National Hospital and the University of Washington are conducting a study to determine the best way to provide PrEP to women in MCH and FP clinics.
- Goal is to identify the best way to reach women who are in need or may benefit from PrEP as an HIV prevention strategy.

Benefits of program:

- The program will help learn the best ways to deliver PrEP to women who need it in Kenya.

Procedures:

Time and Motion

- Participants may also be asked to carry a form for providers to note the start and end time of each service they receive.

Exit Survey

- We will ask questions about knowledge of PrEP and experiences at the clinic.

The risks and discomfort related to this program:

- Participants may feel uncomfortable answering some of the questions today. There are no correct answers and we want to know their thoughts and opinions.
- All efforts shall be made to keep information private and confidential. We will not collect or record participant names today to help keep responses private.

Benefits: Compensation

- **There is no compensation for participation**

Confidentiality of Research Information

The information provided will be kept secret by the study staff. We will not publish or discuss in public anything that could identify participants.

Other information:

- A description of this clinical trial will be available on <http://wwwclinicaltrials.gov>, as required by US 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.
- participation in this study is voluntary.
- Participants do not have to be in this study if they do not want to,
- Answer any questions they may have and give them clinic contact information for future questions.

Final Step:

- ***Ensure the participant understands what the survey is about and if they have any questions***
- After you answer their questions verbally confirm that they agree to participate in the survey today.

All participants:

- Confirm the participant is willing to participate, remind them they are not forced to participate in any activities and may choose not to answer any question at any time.***

