

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

**NCT#:** 04712994

**Principal Investigator:** Grace John-Stewart, MD, PhD, MPH

**Document Name:** Oral Consent Guide

**IRB Approval Date:** December 17, 2020

## Oral Consent Guide

Investigators

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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://www.clinicaltrials.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.**

