

Preparing for a clinical trial of interventions to maintain normal vaginal microbiota for preventing adverse reproductive health outcomes in Africa.

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Participant Identification Number

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Participant Initials

Protocol version 1.0 dated 22 April 2015

VMB trial

ENROLMENT INFORMED CONSENT FORM

Before you sign this consent form (or give your thumbprint or special mark, if you are unable to read), make sure of the following:

- You have read the participant information sheet, or someone has read it to you.
- You have been given a copy of the screening participant information sheet version 1.0 dated 24 April 2015.
- This study has been explained to you.
- The procedures for long-term storage of samples have also been explained to you.
- You have had your questions answered.
- You understand you can ask more questions at any time and that you can withdraw at any time from the study process.
- You understand your study records will be available to the research centre staff and other groups of people.
- You agree to join the study.

PARTICIPANT CONSENT FOR STUDY ENROLMENT

My signature (or thumbprint) below confirms that I freely agree to **join** the VMB trial.

<u>Participant's Name</u>	<u>Participant's Signature/Thumbprint</u>	<u>Date</u>

PARTICIPANT CONSENT FOR FREQUENT SELF-SAMPLING

My signature (or thumbprint) below confirms that I freely agree to be part of the frequent self-sampling group should I be selected.

<u>Participant's Name</u>	<u>Participant's Signature/Thumbprint</u>	<u>Date</u>

PARTICIPANT CONSENT FOR LONG TERM STORAGE OF SAMPLES

My signature (or thumbprint) below confirms that I freely agree that my samples are stored after the final study report for future testing approved by the concerned Ethics Committee, with the exception for genetic testing.

<u>Participant's Name</u>	<u>Participant's Signature/Thumbprint</u>	<u>Date</u>

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IMPARTIAL WITNESS in the event the participant is unable to read

My signature here confirms that I saw the participant being informed about the study. She freely consented verbally and by marking this form to join for the VMB trial.		
<u>Witness Name</u>	<u>Signature</u>	<u>Date</u>

LEGAL GUARDIAN in the event the participant is above 18 but under the age of 21 years and not married

My signature (or thumbprint) here confirms that I agree that the participant takes part in the study. I also confirm that I saw the participant being informed about the study and she gave her free assent to screen for the VMB trial verbally, and by marking this form.		
<u>Legal Guardian Name</u>	<u>Signature/Thumbprint</u>	<u>Date</u>

INVESTIGATOR

As Investigator, or properly delegated by the investigator, I have fully informed the participant of all aspects of the study.		
<u>Investigator/Designee Name</u>	<u>Signature</u>	<u>Date</u>