

MTN-025 (HOPE) Enrollment Informed Consent Comprehension Assessment

Instructions: The assessment should be administered by the study staff member to the potential participant after the informed consent discussion is completed but before the participant is asked to sign or mark the informed consent form. The staff member administering the assessment should read the questions/statements below and mark the required points of comprehension.

| PTID or Name: | | Date: | |
|---|---|-------|----------|
| Question/Statement | Required Points of Comprehension | ✓ | Comments |
| Nkusaba ombulire ky'otegeera ku byava mu kunoonnyereza kwa ASPIRE | The dapivirine vaginal ring prevented about one-third of HIV infections overall. | | |
| | The dapivirine vaginal ring was safe, meaning it did not cause health problems. | | |
| Kiki ekigendererwa ky'okunonyereza kwa HOPE? | To offer eligible participants access to the dapivirine vaginal ring as an HIV prevention method. | | |
| | To collect additional information about safety and adherence of the dapivirine vaginal ring | | |
| Nkusaba ombulire ku buweta obw'okunonyereza mu HOPE. | All vaginal rings contain the study medication (dapivirine). | | |
| Kiki ky'osabibwa okukola mu kunoonnyereza kuno? | Be offered a dapivirine vaginal ring to use monthly for about one year. | | |
| | Study procedures will be similar whether or not you choose the ring as an HIV prevention method. | | |
| | Come to monthly clinic visits for the first 3 months, and then visits every three months for the rest of the study. | | |
| | Have examinations and blood and urine tests, including HIV and pregnancy tests. | | |
| | Receive counseling and answer questions about the vaginal ring and your sexual behaviors. | | |
| | Some participants may be asked to have in-depth interviews or group discussions which are recorded. | | |
| Buzibu ki obuyinza okuva mu kwetaba mukunonyereza? | Vaginal irritation, discomfort, or discharge, discomfort from exams or blood draws, potential HIV drug resistance (must mention at least one) | | |
| | Others may find out about your participation or treat you badly for being in the study (social harms) | | |
| Kiki ekinabaawo singa osalawo obutetaba mu kunoonnyereza? | Free to make own decision about joining the study and can withdraw from the study at any time | | |
| Amawulire agakukwatako ganakuumbwa galya? | Information about participants is confidential and locked away | | |
| | Only people working on the study have access to participant information | | |
| Miganyulo ki egiyinza okuva mu kwetaba mu kunoonnyereza? | Access to the dapivirine vaginal ring as an HIV prevention option. | | |
| | Counseling, condoms, medical exams and tests, and clinical care (must state at least one) | | |
| Kiki kyolina okukola singa obeera nebibuuzo oba ebikwerarikiriza ebikwata ku bulamu bwo oba kubikwata kubigenda mu maaso mu kunoonnyereza? | Must state how to contact study staff (i.e. by phone, return to clinic) | | |

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| | |
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| <p>Outcome:</p> <ul style="list-style-type: none"><input type="checkbox"/> Demonstrated comprehension of all required points, decided to enroll in study<input type="checkbox"/> Demonstrated comprehension of all required points, decided <u>NOT</u> to enroll in study<input type="checkbox"/> Demonstrated comprehension of all required points, deferred enrollment decision<input type="checkbox"/> Did not demonstrate comprehension of all required points, needs more time/discussion<input type="checkbox"/> Unable to demonstrate comprehension of all required points, consent process discontinued<input type="checkbox"/> Other specify): _____ <p>Staff Signature: _____ Date: _____</p> | <p>Optional Comment Codes:</p> <ul style="list-style-type: none">a. Answered correctly on first tryb. Could not answer at first but answered correctly with probingc. Answered incorrectly at first but answered correctly after discussiond. Not able to answer correctly at this timee. Other (describe) |
|---|---|