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| **Instructions** |  | **Comment Code** | |
| 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. |  | **A** | Answered correctly on first try |
|  | **B** | Could not answer at first but answered correctly with probing |
|  | **C** | Answered incorrectly at first but answered correctly after discussion |
|  | **D** | Not able to answer correctly at this time |
|  | **E** | Other (describe) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| **Open-Ended Question/Statement** | | **Required Points of Comprehension** | **Assessed (✓)** | **Comments**  **(Enter code or other notes)** |
| **1** | **Please tell me your understanding of the purpose of the REACH study.** | To collect additional information about if the dapivirine vaginal ring and the Truvada tablet are safe for and acceptable to young women as an HIV prevention method. |  |  |
| To understand how young women use the products in the study. |  |
| **2** | **What are participants being asked to do in this study?** | Use an effective contraceptive method for at least two months prior to study enrollment and for duration of study (about 1.5 years). |  |  |
| Use the monthly dapivirine vaginal ring and take Truvada tablets daily for 6 months each in an assigned order, then choose an HIV prevention method (ring, tablet, or neither) for the last 6 months of the study. |  |
| Come to the clinic monthly for study procedures and new study product; check-in one week after each new product use period (every 6 months). |  |
| Have physical and pelvic exams, and collect vaginal fluid, blood, and urine for tests, including for HIV and pregnancy. |  |
| Receive counseling and answer questions about the vaginal ring and Truvada tablet and your sexual behaviors. |  |
| Some participants may be asked to have in-depth interviews or group discussions, which are recorded. |  |
| **3** | **What are the possible risks of study participation?** | Dapivirine Vaginal Ring: Pain or discomfort in genital area or other side effects, discomfort from exams or blood draws *(must mention at least one)* |  |  |
| Truvada: Body pain or weakness, headaches, or abdominal/stomach side effects for the first few weeks of use *(must mention at least one)* |  |
| Others may find out and treat you badly for being in the study (social harms). Embarrassment and anxiety about discussions and test results. |  |
| **4** | **What will happen if a young women decides not to join the study?** | Free to make her own decision about joining the study. |  |  |
| No change to her access to health care whether she joins the study or not. |  |
| **5** | **How will information about participants in the study be protected?** | Information about participants is confidential, private, and locked away |  |  |
| Only people working on the study have access to her information |  |
| **6** | **What are the possible benefits for participants in the study?** | Counseling, medical exams, tests, clinical care, condoms *(must mention at least one)* |  |  |
| Access to the dapivirine vaginal ring and Truvada as HIV prevention options. |  |
| **7** | **What should participants do if they have questions or concerns about their health or the study?** | *Must state how to contact study staff (i.e. by phone, return to clinic)* |  |  |

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| **Outcome** |
| * Demonstrated comprehension of all required points, decided to enroll in study. * Demonstrated comprehension of all required points, decided NOT to enroll in study. * Demonstrated comprehension of all required points, deferred enrollment decision. * Did not demonstrate comprehension of all required points (yet), needs more time/discussion. * Unable to demonstrate comprehension of all required points, consent process discontinued. * Other (specify)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
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| **Staff Signature** |  | **Staff Date** |  |