|  |  |  |  |
| --- | --- | --- | --- |
| **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) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Open-Ended Question/Statement** | | **Required Points of Comprehension** | **Assessed (✓)** | **Comments**  **(Enter code or other notes)** |
| **1** | **What is the purpose of the DELIVER study?** | To find out if using the dapivirine vaginal ring or oral Truvada during pregnancy is safe and well-tolerated by women and their babies. |  |  |
| **2** | **Please tell me about the study products** | Both study products contain anti-HIV medication and reduce the risk of HIV infection. Neither product can guarantee protection from HIV. |  |  |
| Participants will use the study product assigned to them for the remainder of their pregnancy. The ring is worn continuously in the vagina and replaced monthly. Truvada is a pill taken once daily by mouth. |  |
| **3** | **How is it decided if participants get the ring or Truvada pills?** | Participants will be assigned to use either the ring or Truvada by chance. Neither participants nor study staff can decide which product participants receive. |  |  |
| More participants will be assigned to the ring than Truvada pills. |  |
| **4** | **How long will participants be in the study?** | Participants will have regular study visits and phone contacts for the remainder of their pregnancy and until 6 weeks postpartum. One of the study visits will occur as soon as possible after delivery (no later than 2 weeks after). |  |  |
| **5** | **What will participants be asked to do during their study visits?** | Have physical and pelvic exams, provide vaginal fluid, blood and urine for testing; allow access to medical records/ health provider. |  |  |
| Receive counseling and answer questions about the ring or Truvada pills and sexual behaviors. |  |
| Some participants may be asked to have one or more longer interviews, which may be audio-recorded. |  |
| **6** | **What are the possible risks of study participation?** | Others may find out about and treat mothers or their infants poorly for being in the study (social harms) |  |  |
| Discomfort or anxiety from exams, blood draws, testing or counseling |  |
| Ring side effects: pain or discomfort in genital area or other side effects *(must mention at least one)* |  |
| Truvada side effects: body pain or weakness, headaches, or abdominal/stomach side effects *(must mention at least one)* |  |

Staff initials and date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **7** | **What will happen if you decide not to join the study?** | Free to make one’s own decision about joining the study. |  |  |
| Infants can only join the study if their mother also enrolls. |  |
| No change in access to health care whether one joins the study or not. |  |
| **8** | **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 participant information. |  |
| **9** | **What are the possible benefits of participating in the study?** | Counseling, medical exams, tests, clinical care, condoms *(must mention at least one)*. Study visits do not replace regular antenatal care. |  |  |
| Access to the ring or oral Truvada as HIV prevention methods. |  |
| **10** | **What should participants do if they have questions or concerns about their health or the study?** | *Must state how to contact study staff and/or antenatal care provider (i.e. by phone, return to clinic)* |  |  |

|  |
| --- |
| **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)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|
|
|
|

|  |  |  |  |
| --- | --- | --- | --- |
| **Staff Signature** |  | **Staff Date** |  |