|  |  |  |  |
| --- | --- | --- | --- |
| **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 infants. |  |  |
| **2** | **Please tell me about the study products and how they relate to your infant’s participation** | Both study products contain anti-HIV medication and reduce the risk of HIV infection. Infants will not use study products but may be exposed to the study drugs from their mother’s use of them. |  |  |
| **3** | **How long will infants be in the study?** | Infants will complete up to 4 study visits over about 12 months. The first infant visit will be scheduled as soon as possible after delivery. |  |  |
| **4** | **What procedures will be done with infants in this study?** | Infants will have physical exams, blood draws, testing for HIV if needed, and routine lab tests. With their mother’s permission, photos may be taken of them. |  |  |
| Mothers will be asked questions about their infant’s health and any medications their infant may be taking. |  |
| **5** | **What are the possible risks to infants of study participation?** | Most procedures done in this study are routine medical procedures and pose little risk to infants. |  |  |
| Pain, discomfort or infection from blood draws. |  |
| Side effects from exposure to study drugs during their mother’s pregnancy. |  |
| Others may find out about and treat mothers or their infants poorly for being in the study (social harms) |  |
| **6** | **What will happen if you do not allow your infant to join the study?** | Free to make own decision about infant’s participation |  |  |
| Mothers can only join the study if their infant is also enrolled. |  |
| No change in access to health care whether infant joins the study or not. |  |
| **7** | **How will information about infants in the study be protected?** | Information is confidential, private, and locked away. |  |  |
| Only people working on the study have access to infants’ information. |  |

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **8** | **What are the possible benefits for infants in the study?** | Medical exams, tests, clinical care *(must mention at least one)*.Study visits do not replace well-baby visits. |  |  |
| Potential protection from HIV through mother’s use of study products. |  |
| **9** | **What should mothers do if they have questions or concerns about their infant’s health or the study?** | *Must state how to contact study staff (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** |  |