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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 (ü)** | **Comments** **(Enter code or other notes)** |
| **1** | **What is the purpose of the B-PROTECTED study?** | To find out if using the dapivirine vaginal ring or oral Truvada is safe and well-tolerated by breastfeeding mothers and their breastfed infants.  |  |  |
| To find out how much drug from the ring or pill when used by breastfeeding mothers is found in the mother’s blood and breastmilk, and their infants’ blood. |  |
| **2** | **Please tell me about the study products**  | Both study products contain anti-HIV medication and reduce the risk of HIV infection.  |  |  |
| Participant mothers will use the study product assigned to them for three months while they breastfeed. The ring is worn continuously in the vagina and replaced monthly. The pills are taken once daily by mouth. |  |
| Infants will not use study products but may be exposed to the study drugs from their mother’s use when breastfed. |  |
| **3** | **How is it decided if mothers in the study get the ring or pills?** | Mothers will be assigned to use either the ring or pills by chance. Neither participants nor study staff can decide which product participants receive.  |  |  |
| More participants will be assigned to the ring than the pills. For every two mothers who receive the ring, one mother will receive the pill. |  |
| **4** | **How long will participants be in the study?** | Mothers and their infants will come for about 8 visits over 4.5 months, starting from today’s visit.  |  |  |
| **5** | **What will mothers be asked to do if they join the study?**  | Breastfeed their infant exclusively for the entire duration of their participation in the study.  |  |  |
| Have physical and pelvic exams; provide vaginal fluid, blood, urine, breast milk for testing; allow access to medical records/ health provider. |  |
| Receive counseling and answer questions about the ring or pills and sexual behaviors. |  |
| Some may be asked to have one or more longer interviews, which may be audio-recorded. |  |
| **6** | **What procedures will be done with infants in the study?** | Infants will have physical exams, blood draws, testing for HIV if needed, and routine lab tests. |  |  |
| Mothers will be asked questions about their infant’s health and any medications their infant may be taking. |  |
| **7** | **What are the possible risks of study participation?**  | Others may find out about study participation and treat mothers or their infants poorly for being in the study (social harms) |  |  |
| Mothers may have discomfort or anxiety from exams, blood draws, testing or counseling. Infants may also experience pain, discomfort, or infection from blood draws. |  |
| Ring side effects for mothers: pain or discomfort in genital area or other side effects *(must mention at least one).* |  |
| Truvada side effects for mothers: body pain or weakness, headaches, or abdominal/stomach side effects *(must mention at least one).* |  |
| Infants may have side effects from exposure to study drugs through breastfeeding. |  |
| **8** | **What will happen if you and your infant decide not to join the study?**  | Free to make your own decision about participation for self and infant. |  |  |
| If joining the study, must enroll as a pair. Mothers cannot join without their infant and infants cannot enroll without their mother.  |  |
| Access to health care is not impacted by study enrollment decision.  |  |
| **9** | **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. |  |
| **10** | **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 postpartum care for the mother or well-baby visits for the baby. |  |  |
| Access to the ring or Truvada may provide HIV protection for the mother and, thus, for infants as well. |  |
| **11** | **What should participants do if they have questions or concerns about their health, their infant’s health, or the study?** | *Must state how to contact study staff and/or antenatal care provider (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** |  |