|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Participant Name or PTID** |  | **Date** |  |  | **Staff Signature** |  | **Staff Date** |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Open-Ended Question/Statement** | **Required Points of Comprehension** | **Assessed (✓)** | **Comments** **(Enter code or notes)** |
| **1** | **What do you understand to be the purpose of this study?**  | To better understand attitudes about the use of two HIV prevention methods, a vaginal ring and an oral tablet, by pregnant and breastfeeding women in Africa  |  |  |
| **2** | **How long will study participation last?** | Participation will consist of one study visit. If necessary, additional visits may take place to complete study procedures |  |  |
| **3** | **What are participants being asked to do in this study?** | **Community FGDs:** Participate in either a group discussion or interview with clinic staff that will be audio recorded**Key Informants:** Participate in an interview with clinic staff that will be audio recorded |  |  |
| **For P and BF Women:** allowing study staff permission to access their health records |  |  |
| Complete one or more questionnaires that will ask general questions about yourself |  |  |
| [FGD/IDI] topics will generally focus on the two HIV prevention methods of interest, the use of vaginal products and oral medications by pregnant and breastfeeding women, and common beliefs and practices related to pregnancy and breastfeeding. |  |  |
| **4** | **What are the potential risks of participating in this study?**  | Embarrassment or discomfort surrounding discussions |  |  |
| Possible discrimination or unfair treatment, if others learn of participation in the study |  |  |
| Potential loss of confidentiality  |  |  |
| **5** | **What will happen if you decide not to join the study?**  | Free to make one’s own decision about participating and can withdraw at anytime |  |  |
| No change in access to services provided by clinic |  |  |
| **6** | **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 and audio recordings |  |  |
| **7** | **What are the potential benefits of participating in this study?**  | There may be no direct benefits |  |  |
| Contributing to HIV prevention research efforts |  |  |
| Referrals to medical or social care services, if needed |  |  |
| **8** | **What should you do if you have questions about your health or the study?** | *Must state how to contact study staff* |  |  |

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| --- | --- | --- |
| **Outcome** |  | **Optional Comment Code** |
| * Demonstrated comprehension of all required points, decided to enroll.
* Demonstrated comprehension of all required points, decided NOT to enroll.
* 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)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
 |  | **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)  |