|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Participant Name or PTID** |  | **Date** (DD/MMM/YYYY) |  |  | **Staff Signature** |  | **Staff Date**  (DD/MMM/YYYY) |  |

**Instructions:** 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.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **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 assess couples’ preferences related to dual purpose prevention (DPP) products that could be used to prevent unintended pregnancies and HIV infection |  |  |
| **2** | **How long will study participation last?** | Most participants will have one study visit. Participants selected for an in-depth-interview (IDI) may require a second study visit. |  |  |
| **3** | **What are participants being asked to do in this study?** | All participants will answer questionnaires individually and with their partner. Answers will be recorded on a computer. |  |  |
| Some participants may be asked to have an IDI with research staff. The discussion will be audio recorded. |  |  |
| Topics participants will be asked about include their relationship, sexual practices, and thoughts around different contraception and HIV prevention products. |  |  |
| **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 |  |  |
| Relationship conflict |  |  |
| **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 and contraception research efforts |  |  |
| Referrals to health 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) |