|  |  |  |  |
| --- | --- | --- | --- |
| **No.** | **Question** | **T** | **F** |
| **1** | The main purpose of this research study is to learn about participants’ experiences using the vaginal film.   | [ ]  | [ ]  |
| **2** | There are no risks to being in this study.  | [ ]  | [ ]  |
| **3** | If I decide to participate, I will be asked to self-insert vaginal films twice (at enrollment and the 4-week visit) during study visits.    | [ ]  | [ ]  |
| **4** | For one month after the first vaginal film is inserted, I will be asked to refrain from using anything in the vagina and to abstain from sexual activities. After the second vaginal film is inserted, there are no restrictions.  | [ ]  | [ ]  |
| **5** | My participation is completely voluntary (my choice). | [ ]  | [ ]  |
| **6** | If I take part in the research study, I will have blood tests to look at my general health, have genital samples collected, and I will be tested for HIV. I will also answer questions about my experience using the vaginal film. | [ ]  | [ ]  |
| **7** | My partner’s participation is also required/mandatory for me to join this study. | [ ]  | [ ]  |

Participant Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_

**ANSWER KEY:**

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| --- | --- | --- | --- |
| **No.** | **Question** | **T** | **F** |
| **1** | The main purpose of this research study is to learn about participants’ experiences using the vaginal film.     | [x]  | [ ]  |
| **2** | There are no risks to being in this study.  | [ ]  | [x]  |
| **3** | If I decide to participate, I will be asked to self-insert vaginal films twice (at enrollment and the 4-week visit) during study visits.    | [x]  | [ ]  |
| **4** | For one month after the first vaginal film is inserted, I will be asked to refrain from using anything in the vagina and to abstain from sexual activities. After the second vaginal film is inserted, there are no restrictions. | [x]  | [ ]  |
| **5** | My participation is completely voluntary (my choice). | [x]  | [ ]  |
| **6** | If I take part in the research study, I will have blood tests to look at my general health, have genital samples collected, and I will be tested for HIV. I will also answer questions about my experience using the vaginal film. | [x]  | [ ]  |
| **7** | My partner’s participation is also required/mandatory for me to join this study. | [ ]  | [x]  |

**Reviewed by:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Result:** [insert site specific language regarding assessment of comprehension according to site SOP]

**Comments:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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