|  |  |  |  |
| --- | --- | --- | --- |
| **No.** | **Question** | **True** | **False** |
|  | If I decide to join this research study, I will be in the study for about 6-13 weeks. |  |  |
| 2 | Using the rectal insert will not cause any side effects at all. |  |  |
| 3 | I may contact the study staff at any time if I have any questions or problems. |  |  |
| 4 | During the study, I will be asked to refrain from certain non-study medications and products and certain sexual activities prior to specific study visits and procedures. |  |  |
| 5 | If I decide not to join this research study, I cannot come to the clinic for other services that are provided here. |  |  |
| 6 | If the study staff determine that I have any medical problems, they will treat me or refer me to available sources of medical care for those problems. |  |  |
| 7 | The rectal insert has been proven to protect men and women from getting HIV. |  |  |
| 8 | The reason for this research study is to find out if applying the insert rectally is safe, how the body absorbs and releases the drugs when inserted rectally and if I find using the insert rectally acceptable. |  |  |
| 9 | My personal information will be available to everyone at the clinic, even if they are not part of the study staff. |  |  |
| 10 | I will receive two doses of the insert over the course of the study, which will be administered rectally by study staff. The first dose will be one insert and the second dose will be two inserts. |  |  |
| 12 | If I do not agree to have my leftover specimens stored for future testing, I cannot be in this research study. |  |  |
| 13 | If I take part in the research study, I will have rectal and vaginal (if female) fluid and tissue samples taken. I will also be tested for HIV and other health problems along with answering questions about my experience using the rectal insert. |  |  |
| 14 | I can join this study even if I am currently or have recently taken part in another study of drugs, medical devices, genital or rectal products or vaccines. |  |  |

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| **Staff Signature** |  | **Staff Date**  **DD/MM/YY** |  |

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ANSWER KEY: