|  |  |
| --- | --- |
| **PTID:**  | **Visit Date:**  |
| **Visit Code:** | **Staff Initials:** |

**Instructions:** *Staff should discuss with each participant the requirements of the study, including restrictions on the use of prohibited products and/or medications as well as sexual practices***.**

* Present to the study visits as scheduled.
* Contact study staff with any questions, issues or concerns.
* Inform study staff of any medications taken during the study.
* Abstain from taking the below-listed prohibited medications:
* Anticoagulant medications
* NSAIDs (nonsteroidal anti-inflammatory drugs)
* Aspirin (over 81 mg per day)
* Any drug that is associated with an increased likelihood of bleeding
* Rectally-administered medications
* Products containing nonoxynol-9 or corticosteroids
* PrEP (oral Truvada®)
* PEP
* CYP3A inducer(s) and/or inhibitor(s)\*
* Hormone-replacement therapy (in pill, injectable or gel form) \*

*\*Reported use of these medications will results in permanent discontinuation of study product and will be considered terminated from the study. Site staff should notify the PSRT.*

* Do not take part in other research studies involving drugs, medical devices, vaccines, or genital or rectal products for the duration of study participation.
* Abstain from inserting any non-study products into the rectum 72 hours prior to and following each clinic visit.
* Abstain from the following prohibited activities, 72 hours prior to and following each clinic visit:
	+ Receptive anal intercourse
	+ Receptive oral anal stimulation (e.g., partner placing their mouth on your anal area/rimming)
	+ Rectal stimulation using fingers
	+ Insertion of any non-study products or objects into your rectum, including:
		- Rectal medications
		- Enemas
		- Lubricants
		- Sex toys (dildos, anal plugs, etc.)
		- Fingers

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

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_