| **Enrollment Visit Checklist**PTID: \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ - \_\_\_ Date: \_\_\_ \_\_\_ -\_\_\_ \_\_\_ \_\_\_-\_\_\_ \_\_\_Visit Type: Enrollment Visit Code: 2.0 |
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| **Procedure** | **Staff Initials**  |
| Confirm participant’s identity, PTID and whether participant’s menses has ended and will not occur during the next 7 days. *[Note: If on menses, reschedule enrollment visit within the window, if applicable]* |  |
| Confirm whether the participant is co-enrolled in another study. 🞎 No ==> CONTINUE. 🞎 Yes ==> STOP. NOT ELIGIBLE.  |  |
| Review informed consent and confirm participant is still interested in continued study participation* WILLING/interested in continue participation==> CONTINUE
* NOT WILLING/ interested in continue participation ==> STOP. NOT ELIGIBLE
 |  |
| Confirm participant is within 45-day screening window🞎 YES==> CONTINUE. 🞎 NO ==> STOP. NOT ELIGIBLE.  |  |
| Explain procedures to be performed at today’s visit. |  |
| Provide available test results from previous visit. |  |
| Review/update locator information and re-assess adequacy:* Adequate locator information ==> CONTINUE
* Inadequate locator information ==> STOP. NOT ELIGIBLE
 |  |
| Administer ***Enrollment Behavioral Eligibility Worksheet***🞎 Eligible ==> CONTINUE. 🞎 **Not Eligible** but **likely** to meet eligibility criteria within this screening attempt ==> PAUSE ==> Reschedule  Enrollment Visit when participant is likely to be eligible.🞎 **Not Eligible** and **Not likely** to meet eligibility criteria within this screening attempt ==> STOP |  |
| Review and update baseline medical, menstrual and medications history. As needed, make updates to ***Baseline Medical History Questions Sheet, Pre-existing Conditions CRF and Concomitant Medications Log CRF.***  Document last menstrual period on the ***Pharmacokinetics Specimens—Enrollment CRF***. |  |
| Provide and document contraceptive counseling using***Contraceptive Counseling Worksheet.*** |  |
| Collect urine (15-60 mL):* **hCG**
* Dipstick urinalysis (if indicated)
* urine culture (if indicated)

Pregnant: 🞎 NO==> CONTINUE 🞎 YES==> **STOP**. NOT ELIGIBLE.Document dipstick urinalysis results on the ***Safety Laboratory Results CRF*,** if indicated**.**  |  |
| Provide and document HIV pre- test and risk reduction counseling *using* ***HIV Pre/Post Test and Risk Reduction Counseling Worksheet*** |  |
| Collect blood: **❒ Complete blood count (CBC) with differential and platelets****❒ HIV-1 serology****Testing is based on local lab requirements; tailor this item to reflect site-specific tube type and volume.****❒ Plasma archive****❒ Chemistries (AST, ALT, creatinine)**❒ Syphilis serology (if indicated)Document results onto ***Safety Laboratory Results CRF*** once available. Document plasma archive collection on the ***Enrollment CRF*** and ***LDMS Tracking Shee***t. |  |
| Provide and document available test results/post-test counseling using ***HIV Pre/Post Test and Risk Reduction Counseling Worksheet.*** |  |
| Perform and document full physical examination on the ***Physical Exam CRF***. Document any relevant conditions to the ***Pre-Existing Conditions CRF***. |  |
| Perform and document pelvic examination using the ***Pelvic Exam Checklist, Pelvic Exam CRF and Pelvic* *Exam Diagrams non-DataFax CRF***. Add any relevant conditions to the ***Pre-Existing Conditions CRF***. Document collection and storage of required specimens on the ***Specimen Storage CRF*** and ***LDMS Tracking Sheet***.  |  |
| Evaluate any abnormal findings. Explain test results and exam findings. If STI/RTI/UTI is diagnosed, provide or refer for treatment. Document provision of results, treatments and referrals in chart notes. Note: Participant must complete treatment and symptoms resolved prior to enrollment *(see protocol for exclusionary STIs i.e. GC/CT and syphilis).*  |  |
| Assess eligibility status by review/completion of ***Eligibility Checklist***. 🞎 **Eligible** ==> CONTINUE. 🞎 Not Eligible but likely to meet eligibility criteria within this screening attempt ==> PAUSE ==> Schedule Enrollment Visit when participant is likely to be eligible.🞎 **NOT ELIGIBLE** and **NOT** likely to meet eligibility criteria within this screening attempt ==> STOP. |  |
| Once eligibility status is confirmed by reviewing and completing the Eligibility Checklist, document the participant’s eligibility status on the ***Eligibility Criteria CRF.*** ***Note****: The IoR or designee should complete item 1a and a second staff verifying eligibility must complete item 1b.*  |  |
| Randomize participant via the FSTRF web randomization system. Print two copies of the FSRTF Randomization Confirmation Email send one to pharmacy along with completed prescription. Complete prescription and send white copy to pharmacy, retain yellow copy in participant chart together with the second copy of the confirmation email. Document the date and time of randomization and randomization number (code) on the ***Enrollment CRF***. |  |
| Review self-swab collection instructions with participant. After all questions and concerns have been addressed, instruct participant to self-collect the vaginal swab for PK for the Hour 0 sample collection. Record collection on the ***Pharmacokinetics Specimens—Enrollment CRF*** and ***LDMS Tracking Sheet*****Note**: This Hour 0 collection should be taken ***prior to***ring insertion.  |  |
| Provide and document protocol and product use adherence counseling using ***Protocol and Product Adherence Counseling Worksheet******Note to site: The review of protocol and product use counseling messages may be placed elsewhere in the visit flow per site discretion.*** |  |
| Review/provide ring insertion and removal instructions with participant, using visual aids as needed. Provide participant with vaginal ring for self-insertion and ask her to insert the ring. Document time and date of vaginal ring insertion on the ***Enrollment CRF***.  |  |
| Have clinician confirm placement of the vaginal ring through digital (bimanual) examination. |  |
| Document the provision of the vaginal ring to the participant using the ***Clinic Study Product Accountability Log*** |  |
| Collect blood for PK at 1, 2, 4, and 6 hours post-ring insertion. Document collection times on the ***LDMS Tracking Sheet.*** Document collection and storage of required specimens on the ***Pharmacokinetics Specimens—Enrollment CRF.*** |  |
| Instruct participant to self-collect vaginal swab for PK (post ring insertion) for the Hours 1, 2, 4, and 6 hours. Document collection times, pre/post/net weights on the ***LDMS Tracking Sheet*.** Document collection and storage of required specimens on the ***Pharmacokinetics Specimens—Enrollment CRF***.**Note**: Vaginal swab for PK should ideally be collected within 5 minutes of PK blood draw.  |  |
| Update ***Screening and Enrollment Log***.  |  |
| Review study schedule using visit schedule tool. Schedule next visit and advise participant of potential length of next visit.  |  |
| Provide reimbursement. |  |

**Complete and assemble all CRFs from the Screening and Enrollment Visit and complete QC 1 to ensure all items are completed (while the participant is still in the clinic). Do not fax forms until participant has enrolled (randomized).**

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| **Screening CRFs** |
| Demographics CRF |
| Pelvic Exam CRF  |
| Physical Exam CRF |
| Pelvic Exam Diagrams (non-DataFax) CRF |
| Safety Laboratory Results CRF |
| **Enrollment CRFs** |
| Pelvic Exam CRF  |
| Physical Exam CRF |
| Enrollment CRF  |
| Pharmacokinetics – Enrollment CRF  |
| Eligibility Criteria CRF |
| Safety Laboratory Results CRF  |
| Specimen Storage CRF |
| Pelvic Exam Diagrams (non-DataFax) CRF |
| Pre-Existing Conditions CRF |
| Concomitant Medications Log CRF |
| **Other Tools and Worksheets** |
| LDMS Tracking Sheet |
| Enrollment Behavioral Eligibility Worksheet |
| Baseline Medical History Questions Sheet |
| Clinic Product Accountability Log |
| HIV Pre/Post Test and Risk Reduction Counseling Worksheet |
| Protocol and Product Adherence Counseling Worksheet |
| Contraceptive Counseling Worksheet (as needed) |
| Screening and Enrollment Log |
| Eligibility Checklist  |

QC1 (Staff Initial): \_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_

QC2 (Staff Initial): \_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_