**Instructions:** Complete staff initials next to procedures completed. Do not initial for other staff members. If other staff members are not available to initial checklist items themselves, initial and date a note on the checklist documenting who completed the procedure, e.g., “done by {name}” or “done by nurse.” If a procedure listed on the checklist is not performed, enter “ND” for “not done” or “NA” for “not applicable” beside the item and record the reason why (if not self-explanatory); initial and date this entry.

| **Enrollment Visit Checklist** |
| --- |
|  **Procedure** | **Staff Initials** | **Comments:** |
| 1. 1
 | Confirm identity and PTID  |  |  |
| 1. 2
 | Check for co-enrollment in other studies:* NOT enrolled in another study ==> CONTINUE.
* Enrolled in another study ==> STOP. NOT ELIGIBLE.
 |  |  |
| 1. 3
 | Confirm participant is within 56-day screening window* WITHIN 56 days from screening visit ==> CONTINUE.
* OUTSIDE 56 days from screening visit ==> STOP. Not eligible to enroll during this screening attempt ==> If willing, schedule for rescreening
 |  |  |
| 1. 4
 | Review/update locator information and re-assess adequacy:* Adequate locator information ==> CONTINUE.
* Inadequate locator information ==> STOP. NOT ELIGIBLE.
 |  |  |
| 1. 5
 | Explain, conduct, and document enrollment informed consent process, including comprehension assessment:* Willing and able to provide written informed consent ==> CONTINUE.
* NOT willing and able to provide written informed consent ==> STOP. NOT ELIGIBLE.
 |  |  |
| 1. 6
 | Administer Enrollment Behavioral Eligibility Worksheet * ELIGIBLE thus far ==> CONTINUE.
* NOT ELIGIBLE ==> STOP.
 |  |  |
| 1. 7
 | Provide and document counseling HIV pre-test counseling  |  |  |
| 1. 8
 | Perform and document two Finger Stick HIV tests *[Note to sites: if your site is not doing finger sticks, edit checklist as needed. Plasma archive and blood for HIV testing can be collected in the same blood draw.]*  |  |  |
| 1. 10
 | Collect urine:* (15-60 mL) for Urine hCG (pregnancy)
* Xxx mL for urine culture, if indicted (per standard of care)
* Xxx mL for NAAT for GC/CT, if indicated
 |  |  |
| 1. 11
 | Collect vaginal fluid for archive (self-collection)  |  |  |
| 1. 12
 | Review/update baseline medical, menstrual, and medications history: review and update Baseline Medical History Log and Concomitant Medications Log CRFs as needed.  |  |  |
|  | If indicated, perform targeted physical exam.  |  |  |
|  | If indicated, perform targeted pelvic exam per Pelvic Exam checklist |  |  |
|  | Administer Family Planning Log CRF. Review study contraception requirements, and provide contraceptive counseling. |  |  |
|  | Review pregnancy test results:* NOT pregnant ==> CONTINUE.
* Pregnant ==> STOP. NOT ELIGIBLE.

Complete Pregnancy Test Result CRF |  |  |
| 1. 13
 | Prescribe contraceptives, if indicated. |  |  |
| 1. 14
 | If STI/RTI/UTI is diagnosed, provide treatment. Update Baseline Medical History Log and Concomitant Medications Log CRFs. Participant must complete treatment and be free of symptoms prior to enrollment.  |  |  |
| 1. 15
 | Provide and explain all available findings and results. Refer for other findings as indicated. |  |  |
| 1. 16
 | Provide HIV test results in the context of post-test counseling. Provide referrals if needed/requested. * If both tests negative ==> UNINFECTED ==> ELIGIBLE ==> CONTINUE.
* If both tests positive ==> INFECTED ==> STOP. NOT ELIGIBLE.
* If one test positive and one test negative ==> DISCORDANT ==> STOP. NOT ELIGIBLE. ==> Submit HIV Query form to inform LC, collect *blood and perform a Geenius confirmatory test and plasma viral load (HIV RNA PCR).*
 |  |  |
|  | Provide and document HIV Prevention Options counseling/protocol counseling, including offering condoms. Does participant choose to use the ring? * Yes
* No
 |  |  |
| 1. 19
 | Conduct confirmation and final determination of eligibility status by review/completion of Eligibility Checklist. * ELIGIBLE ==> CONTINUE ==> sign the Eligibility Checklist and proceed to eligibility verification
* NOT ELIGIBLE ==> STOP. DO NOT enroll. ==> Pause and evaluate whether participant is:
	+ NOT ELIGIBLE but likely to meet eligibility criteria within this screening attempt ==> PAUSE ==> perform and document all clinically indicated procedures. Schedule another Enrollment Visit when participant is likely to be eligible.
	+ NOT ELIGIBLE and NOT likely to meet eligibility criteria within this screening attempt ==> STOP. Provide clinical management as needed. Complete the Eligibility Criteria CRF.
 |  |  |
| 1. 20
 | Verify participant eligibility by review of Eligibility Checklist (must be different staff member than step 21): * ELIGIBLE ==> CONTINUE 🡪 sign the Eligibility Checklist.
* NOT ELIGIBLE ==> STOP. DO NOT enroll. Provide clinical management as needed.

**Participant considered is enrolled once eligibility checklist is completed and final sign off is completed by designated staff.**  |  |  |
|  | For participants who accept the ring, complete prescription and send to pharmacy. |  |  |
| 1. 21
 | Collect blood for plasma archive and send to lab *[Note: if site is not doing finger stick, collect this sample with blood for HIV testing, edit checklist as appropriate]:** X x X mL lavender top (EDTA) tube, for plasma archive
 |  |  |
| 1. 22
 | Administer Baseline ACASI Questionnaire. |  |  |
| 1. 23
 | Administer Baseline Behavior Assessment CRF and Baseline Vaginal Practices CRF |  |  |
| 1. 26
 | **For participants who accept the ring**:* Provide ring use instructions and review important information
 |  |  |
| * Provide participant with vaginal ring for self-insertion and ask her to insert the ring. Document the provision of the vaginal ring to the participant using the Study Product Accountability Log
 |  |  |
| * As indicated, confirm placement of the vaginal ring through digital examination
 |  |  |
| * De-brief with participant about her first study product use experience *[document in chart notes]*: • Was she able to insert the ring?• Did she have any difficulties? • Does she have any questions or concerns about ring use?• Would she like any additional information or instructions?
 |  |  |
|  | Generate participant visit calendar if not done already. |  |  |
| 1. 27
 | Schedule Month 1 visit. Provide contact information and instructions to report symptoms and/or request information, counseling, a new ring (if applicable), or condoms before next visit. |  |  |
| 1. 28
 | Perform QC1: while participant is still present, review the following for completion:* Enrollment Behavioral Eligibility
* Eligibility Checklist
* Family Planning Log
* Baseline Behavior Assessment
* Baseline Vaginal Practices
* Enrollment Visit LDMS Specimen Tracking Sheet
* Baseline Medical History Log
 |  |  |
| 1. 29
 | Update co-enrollment database and participant tracking database (or site-specific tracking documents).  |  |  |
|  | Update Screening and Enrollment Log |  |  |
| 1. 30
 | Provide reimbursement |  |  |
| 1. 31
 | For enrolled participants, QC and then submit all required Case Report Forms from the Screening and Enrollment visits into Medidata Rave.**From Screening Visit:*** Demographics
* Pelvic Exam
* Vital Signs
* Physical Exam
* Laboratory Results
* STI Results
* Eligibility Criteria

**Enrollment Visit:*** Enrollment
* Pregnancy Test Result
* Specimen Storage
* ACASI Tracking
* Ring Collection and Insertion
* Baseline Behavior Assessment
* Baseline Vaginal Practices

**Log CRFs*** Baseline Medical History Log
* Concomitant Medications Log
* Family Planning Log
* Vaginal Ring Tracking Log

If participant not enrolled for this screening attempt, complete and submit Eligibility Criteria in Medidata Rave.  |  |  |