**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 | Confirm identity and PTID and whether she is on her menses currently. *[If on menses, reschedule enrollment within the screening window, if possible.]* |  |  |
| 2 | Check for co-enrollment in other studies:* NOT enrolled in another study ==> CONTINUE.
* Enrolled in another study ==> STOP. NOT ELIGIBLE.
 |  |  |
| 3 | Confirm participant is within 28-day screening window* WITHIN 28 days from screening visit ==> CONTINUE.
* OUTSIDE 28 days from screening visit ==> STOP. Not eligible to enroll during this screening attempt ==> If willing, schedule for rescreening (Note: Only two screening attempts allowed)
 |  |  |
| 4 | Review/update locator information and re-assess adequacy:* Adequate locator information ==> CONTINUE.
* Inadequate locator information ==> STOP. NOT ELIGIBLE.
 |  |  |
| 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.
 |  |  |
| 6 | Administer Enrollment Behavioral Eligibility CRF * ELIGIBLE thus far ==> CONTINUE.
* NOT ELIGIBLE ==> STOP.
 |  |  |
| 7 | Provide and document counseling:* HIV pre-test counseling
* HIV/STI risk reduction counseling
* Provide Condoms
 |  |  |
| 8 | Provide enrollment adherence counseling (ring use education). Review ring insertion instructions with participant in detail, using visual aids as needed.  |  |  |
| 9 | 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 serology can be collected in the same blood draw.]*  |  |  |
| 10 | 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. ==> Contact NL for follow-up
 |  |  |
| 11 | Collect urine (15-60 mL) and send to lab for Urine hCG (pregnancy) |  |  |
| 12 | Collect vaginal fluid for archive (self-collection) [*Note: Only once LoA#2 is approved.]* |  |  |
| 13 | Review/update baseline medical, menstrual, and medications history: review Pre-existing Conditions, Screening Menstrual History CRF (item 8) and Concomitant Medications Log CRFs.  |  |  |
| 14 | Administer Baseline Family Planning CRF. Review study contraception requirements, and provide contraceptive counseling. |  |  |
| 15 | Prescribe contraceptives, if indicated  |  |  |
| 16 | Review pregnancy test results:* NOT pregnant ==> CONTINUE.
* Pregnant ==> STOP. NOT ELIGIBLE.
 |  |  |
| 17 | Perform targeted physical exam. Complete Enrollment Abbreviated Physical Exam CRF.  |  |  |
| 18 | If indicated, perform and document pelvic exam per Source Documentation SOP. Do not collect gram stain or endocervical specimens.Update PRE CRF accordingly. If a full pelvic exam is conducted, complete a new SPE-1 in addition to the Pelvic Exam Diagrams CRF. |  |  |
| 19 | If STI/RTI/UTI is diagnosed, provide treatment. Update Pre-existing Conditions and Concomitant Medications Log CRFs. Participant must complete treatment and be free of symptoms prior to enrollment.  |  |  |
| 20 | Provide and explain all available findings and results. Refer for other findings as indicated. |  |  |
| 21 | Conduct confirmation and final determination of eligibility status by review/completion of Eligibility Checklist. * ELIGIBLE thus far ==> CONTINUE ==> sign item 1a on ECI-1 CRF and proceed to eligibility verification
* NOT ELIGIBLE ==> STOP. DO NOT RANDOMIZE. ==> 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 and fax Eligibility Criteria CRF.
 |  |  |
| 22 | Verify participant eligibility by review of Eligibility Checklist (must be different staff member than step 21): * ELIGIBLE thus far ==> CONTINUE ==> sign item 1b on ECI-1 CRF
* NOT ELIGIBLE ==> STOP. DO NOT RANDOMIZE. Provide clinical management as needed.
 |  |  |
| 23 | Collect blood for plasma archive and send to lab *[Note: if site is not doing finger stick, collect this sample with blood for HIV serology, edit checklist as appropriate]:** X x X mL lavender top (EDTA) tube, for plasma archive
 |  |  |
| 24 | Administer Baseline ACASI Questionnaire. |  |  |
| 25 | Administer Baseline Behavioral Assessment and Baseline Vaginal Practices CRFs |  |  |
| 26 | Randomize participant by assigning next sequential prescription (based on Randomization Number). **PARTICIPANT IS NOW ENROLLED IN THE STUDY.** Complete prescription and send to pharmacy. |  |  |
| 27 | Update the Study Product Accountability Log accordingly |  |  |
| 28 | Review ring insertion instructions as needed. Provide participant with vaginal ring for self-insertion and ask her to insert the ring.  |  |  |
| 29 | Confirm placement of the vaginal ring through digital examination. |  |  |
| 30 | Have participant attempt to remove and reinsert the vaginal ring herself. |  |  |
| 31 | 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? |  |  |
| 32 | *[Sites to insert as applicable per site practice]:* As needed, provide bottle of water for rinsing vaginal ring. |  |  |
| 33 | Schedule Month 1 visit and advise her of potential length of the visit. Provide contact information and instructions to report symptoms and/or request information, counseling, a new ring, or condoms before next visit. |  |  |
| 34 | Perform QC1: while participant is still present, review the following for completion:* Enrollment Behavioral Eligibility
* Eligibility Checklist
* Baseline Family Planning
* Baseline Behavior Assessment
* Baseline Vaginal Practices
* Enrollment Visit LDMS Specimen Tracking Sheet (non-DataFax)
* Pre-existing Conditions CRF
 |  |  |
| 35 | Update co-enrollment database, Screening and Enrollment Log, and participant tracking database (or site-specific tracking documents). Generate participant visit calendar if not done already. |  |  |
| 36 | Provide reimbursement |  |  |
| 37 | For enrolled participants, QC and then Fax all required DataFax forms from the Screening and Enrollment visits to SCHARP DataFax.**From Screening Visit:*** Demographics
* Screening Pelvic Exam
* Screening Visit Physical Exam
* Screening Menstrual History
* Screening Laboratory Results
* Screening Specimen Storage
* Screening STI Results

**Enrollment Visit:*** Enrollment
* Eligibility Criteria
* Baseline Family Planning
* Prior Trial Participation
* Baseline Behavior Assessment
* Baseline Vaginal Practices
* Enrollment Abbreviated Physical Exam

**Log CRFs*** Pre-existing Conditions
* Concomitant Medications Log

If participant not enrolled for this screening attempt, complete and fax Eligibility Criteria to SCHARP DataFax.  |  |  |