**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. |  |  |