**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. |  |  |