| **Enrollment Visit (Visit 2.0) Checklist** |
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|  **Procedure** | **Staff Initials** | **Comments:** |
|  | Confirm identity and PTID  |  |  |
|  | Check for co-enrollment in other studies:* NOT enrolled in another study ==> CONTINUE.
* Enrolled in another study ==> STOP. NOT ELIGIBLE.
 |  |  |
|  | Confirm participant is within 45-day screening window* WITHIN 45 days from screening visit ==> CONTINUE.
* OUTSIDE 45 days from screening visit ==> STOP. Not eligible to enroll
 |  |  |
|  | Review/update locator information using site-specific form. Re-assess adequacy:* Adequate locator information ==> CONTINUE.
* Inadequate locator information ==> STOP. NOT ELIGIBLE.
 |  |  |
|  | Review elements of informed consent. Explain procedures to be performed at today’s visit. Confirm participant is still willing to participate:* Willing to participate ==> CONTINUE.
* NOT willing to participate==> STOP. NOT ELIGIBLE.
 |  |  |
|  | Assess participant behavioral eligibility using the Enrollment Behavioral Eligibility Worksheet* ELIGIBLE thus far ==> CONTINUE
* NOT ELIGIBLE but likely to meet eligibility criteria within this screening attempt ==> PAUSE ==> Re-schedule Enrollment Visit when participant is likely to be eligible.
* NOT ELIGIBLE and NOT likely to meet eligibility criteria within this screening attempt ==> STOP
 |  |  |
|  | Provide available test results from screening visit. Treat and/or refer for care as required. |  |  |
|  | Administer Vaginal Practices CRF |  |  |
|  | Administer Baseline CASI Questionnaire |  |  |
|  | Provide and document the following on appropriate counseling worksheets or [*site-specific source document*]. Provide male condoms if needed.* Protocol adherence counseling
* HIV/STI risk reduction counseling (and male condom counseling if indicated)
* HIV pre and post-test counseling if indicated
 |  |  |
|  | Review/update baseline medical and medications history, Baseline Medical History Questions Sheet, Pre-existing Conditions and Concomitant Medications Log CRFs.  |  |  |
|  | If clinically indicated, collect (15-60 mL) urine. * hCG (pregnancy testing)
* Dipstick urinalysis and/or urine culture
 |  |  |
|  | If clinically indicated, review pregnancy test results:* NOT pregnant ==> CONTINUE.
* Pregnant ==> STOP. NOT ELIGIBLE.
 |  |  |
|  | Perform physical exam. Complete Physical Exam CRF.  |  |  |
|  | Perform and document pelvic exam per Pelvic Exam Checklist.  |  |  |
|  | 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.  |  |  |
|  | Provide and explain all available findings and results. Refer for other findings as indicated. |  |  |
|  | Conduct confirmation and final determination of eligibility status by completing the ‘Enrollment Visit’ column of the Eligibility Checklist. * ELIGIBLE thus far ==> CONTINUE ==> proceed to eligibility verification
* NOT ELIGIBLE ==> STOP. DO NOT RANDOMIZE.

If participant will proceed to Enrollment, complete Eligibility Criteria CRF. |  |  |
|  | Collect blood for:* Plasma Archive [10 mL]

Note: Plasma archive must be collected prior to randomization.If clinically indicated: **Testing is based on local lab requirements; tailor this item to reflect site-specific tube type and volume.*** HIV serology
* Serum Chemistries
* CBC with platelets

If indicated, review HIV test results:* HIV negative ==> CONTINUE.
* HIV positive ==> STOP. NOT ELIGIBLE.

Document results on Enrollment, Safety Laboratory Results and HIV Results CRFs if indicated.  |  |  |
|  | Randomize participant by assigning next randomization envelope. Complete Randomization Envelope Tracking Record. **PARTICIPANT IS NOW ENROLLED IN THE STUDY.** Complete prescription and send to pharmacy.Was participant randomized to the in-depth interview?* Yes
* No
 |  |  |
|  | 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.  |  |  |
|  | 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 and Ring Collection and Insertion CRF.  |  |  |
|  | De-brief with participant about her first study product use experience *[document on Ring Use Adherence Key Messages Worksheet or site specific document]* |  |  |
|  | Provide ring use adherence counseling [*document on Ring Use Adherence Key Messages Worksheet or site specific document*] |  |  |
|  | Schedule 4 -Week Follow Up 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.  |  |  |
|  | If needed, provide study approved lubricant and Study-Approved Lubricant Use Log with instructions to complete if she chooses to use study-provided lubricant provided within the 72 hours prior to your next clinic visit. |  |  |
|  | Perform QC1: while participant is still present, review the following for completion:* Eligibility Checklist
* Pre-existing Conditions CRF
 |  |  |
|  | Document all stored specimens on the Specimen Storage CRF and LDMS Specimen Tracking Sheet |  |  |
|  | Update Screening and Enrollment Log and or site-specific tracking documents. Generate participant visit calendar if not done already. |  |  |
|  | Remind the participant that she will be contacted via phone in one week to follow up on any problems or concerns |  |  |
|  | Provide reimbursement |  |  |
|  | For enrolled participants, conduct QC2 and then Fax all required DataFax forms from the Screening and Enrollment visits to SCHARP DataFax.**From Screening Visit:*** Demographics
* Pelvic Exam
* Physical Exam
* Safety Laboratory Results
* STI Test Results
* HIV Results
* Pelvic Exam Diagrams (non-DataFax)

**Enrollment Visit:*** Enrollment
* Eligibility Criteria
* Ring Collection and Insertion
* Vaginal Practices
* Physical Exam
* Pelvic Exam
* Specimen Storage
* STI Test Results (if needed)
* Pelvic Exam Diagrams (non-DataFax)

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

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