**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. If any procedures are not conducted on the date recorded above, ensure the date procedure conducted is included in the comments section.

| **Procedure** | **Staff Initials** | **Comments:** |
| --- | --- | --- |
|  | Confirm identity, age, and PTID |  |  |
|  | Check for co-enrollment * NOT currently or recently enrolled in another study 🡪 CONTINUE.
* Currently or recently enrolled in another study 🡪 STOP. Assess eligibility to continue.

*NOTE: Participation in studies involving drugs, medical devices, vaginal products, or vaccines within 60 days of enrollment is exclusionary.*   |  |  |
|  | 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 during this screening attempt --> If willing, schedule for rescreening\*

*\* Participant may only re-screen once per protocol section 7.2* |  |  |
|  | Review/update locator information and 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.
 |  |  |
|  | Log into Medidata Rave database, and select the appropriate PTID. Begin visit by opening the Enrollment Visit folder. |  |  |
|  | Provide and explain all prior screening test results.  |  |  |
|  | Assess behavioral eligibility by administering the **Enrollment Behavioral Eligibility Worksheet** * ELIGIBLE thus far 🡪 CONTINUE.
* NOT ELIGIBLE 🡪 STOP.
 |  |  |
|  | Administer the Baseline CASI assessment and document on the **Behavioral Assessments Summary CRF** and **CASI Tracking CRF**. |  |  |
|  | Conduct protocol counseling with participant and document on **Protocol Counseling Worksheet**. Give participant the Study Adherence Guide to take home. |  |  |
|  | Collect urine (15-60 mL) and perform tests:* Qualitative hCG (pregnancy)
* Dipstick urinalysis and/or culture per site SOP, ***if indicated***

*NOTE: If symptomatic and diagnosed with a UTI, the participant must complete treatment and all symptoms must resolve to be eligible for enrollment.* |  |  |
|  | Confirm pregnancy results:* NOT pregnant 🡪 CONTINUE.
* Pregnant 🡪 STOP. NOT ELIGIBLE.

Complete [add site-specific laboratory testing source document] and **Pregnancy Test Results CRF** upon receipt of lab test results. |  |  |
|  | Confirm contraceptive method use for at least 30 days prior to Enrollment, review study contraception requirements, and provide contraceptive counseling. Effective study methods per study protocol include: * hormonal methods (except contraceptive ring)
* IUD
* sterilization (of participant or partner, as defined in site SOPs)
* having sex exclusively with individual assigned female at birth
* abstinence from PVI for 90 days prior to Enrollment and intending to remain abstinent from PVI during study participation
* Meets contraceptive requirements ⇒ CONTINUE.
* DOES NOT meet contraceptive requirements ⇒ STOP. NOT ELIGIBLE.

[Prescribe/provide/refer for] contraception if needed; document in chart notes and **Protocol Counseling Worksheet.** |  |  |
|  | Administer and document HIV pre-test and HIV/STI risk reduction counseling, including offering male condoms,\* using the **HIV Pre/Post Test and Risk Reduction Counseling Worksheet**.\*if indicated and/or per local standard of care |  |  |
|  | Review participant’s baseline medical, menstrual, and current medications, to verify and/or update all information recorded at the Screening Visit. Document all updates as needed on:* **Relevant source documents**
* **Medical History CRF**
* **Concomitant Medications CRF**

Record last menstrual period dates: **First day: \_\_\_\_\_\_\_\_\_\_\_\_ Last Day: \_\_\_\_\_\_\_\_** |  |  |
|  | Determine whether participant has current RTI/STI/UTI symptoms:* No symptoms ⇒ CONTINUE.
* Symptom(s) present ⇒ evaluate per site SOPs. Treat or refer for treatment if required\* ⇒ STOP. MAY BE INELIGIBLE.

Document provision of results, treatment and/or referrals in chart notes.*\* If symptomatic and is diagnosed with an RTI/STI/UTI, the participant must complete treatment and all symptoms must resolve to be eligible for enrollment. Treat if indicated per site SOP.* |  |  |
|  | Perform a targeted physical exam and complete the **Vital Signs CRF** and **Physical Exam CRF.** |  |  |
|  | Collect the following amounts of blood and send to lab for testing:* HIV-1/2
	+ [X] mL [color] top [additive/no additive] tube
* HSV 1/2 serology
	+ [X] mL [color] top [additive/no additive] tube
* Plasma for archive (MTN LC)
	+ 10 mL lavender top EDTA tube

***If indicated**** CBC with platelets and differentials
	+ [X] mL [color] top [additive/no additive] tube
* Serum creatinine
	+ [X] mL [color] top [additive/no additive] tube
 |  |  |
|  | Perform and document a pelvic exam per the Pelvic Exam Checklist, including pelvic specimen collection for* Vaginal swabs for microbiota
* Vaginal Gram Stain
* CVF for anti-HSV-2 activity and biomarkers
* CVL for PD and biomarkers

Document on **Pelvic Exams Diagram,** **Pelvic Exam CRF,** and **Timed Cervical Specimen CRF.** |  |  |
|  | Provide HIV test results in the context of post-test counseling and document on **HIV Pre/Post Test and HIV/STI Risk Reduction Counseling Worksheet.** Provide referrals if needed/requested per site SOPs. * If negative 🡪 UNINFECTED 🡪 CONTINUE.
* If positive or indeterminate 🡪 STOP. Perform HIV confirmation test actions per HIV testing algorithm to determine eligibility

Document HIV test results on **HIV Test Results CRF.**  |  |  |
|  | Evaluate findings identified during pelvic and physical examinations and medical history review. Document in chart notes and relevant conditions on the **Medical History CRF** and **Concomitant Medications CRF.**Provide and explain all available findings and results. Refer for other findings as indicated. |  |  |
|  | 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. Complete the **Inclusion/Exclusion Criteria CRF.**
* 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 **Inclusion/Exclusion Criteria CRF.**
 |  |  |
|  | Verify participant eligibility by review of **Eligibility Checklist** (done by IoR or designee [must be different staff member from above step]): * ELIGIBLE 🡪 CONTINUE
* NOT ELIGIBLE 🡪 STOP. DO NOT RANDOMIZE. Provide clinical management as needed.
 |  |  |
|  | Randomize the participant to VR arm and cervical tissue sampling schedule by completing the **Randomization CRF**. Once the participant’s randomization date and time auto-populates on the Randomization CRF, the participant is randomized. ONCE RANDOMIZED, THE PARTICIPANT IS OFFICIALLY ENROLLED IN THE STUDY. |  |  |
|  | Verify participant’s status for completing an In-depth Interviews (IDI). Determine if the participant should be invited for an IDI through review of the IDI randomization listing and Demographic CRF. If the participant meets the invitation criteria, invite the participant for an IDI, and explain the IDI process and schedule. *Note: participant should be invited if she is randomized to an IDI and her response to the Demographics CRF question* “In the past 12 months, with whom did the participant have vaginal sex:”*?” is “Both male and female partners” or “Exclusively male partners”.*Confirm his/her verbal willingness to participate and be audio-recorded. * AGREES TO IDI
* DECLINES TO PARTICIPATE
* NOT INVITED (randomized, but does not meet invitation criteria)
* N/A (not randomized to IDI)

Document selection outcome on **Enrollment CRF.** |  |  |
|  | Complete the **MTN-038 Study Ring Prescription** for participant.* Deliver the top (white) copy along with the [site-specific form] to the pharmacy.
* Retain yellow copy of prescription in participant’s binder.
 |  |  |
|  | Retrieve study VR and white return bag (for used VR) from pharmacy |  |  |
| Provide VR use instructions and review important information. Give participant white return bag to take home. |  |  |
| Have participant (or clinician/designee, if necessary) insert VR.  |  |  |
| Perform digital (bimanual) exam to check VR placement. |  |  |
| Document the provision of the VR to the participant using the **Site-Specific** **Clinic Study Product Accountability Log** and **Ring Insertion and Removal CRF.**  |  |  |
|  | **At 1 hour (+/- 15min) after VR insertion,** collect CVF for TFV* 1 swab near the site of the VR

Document on the **Timed Cervical Specimen Storage CRF** and **LDMS Tracking Sheet;** record pre- and post-collection weights. |  |  |
|  | **At 4 hours (+/- 15min) after VR insertion,** collect CVF for TFV* 1 swab near the site of the VR

Document on the **Timed Cervical Specimen Storage CRF** and **LDMS Tracking Sheet;** record pre- and post-collection weights. |  |  |
|  | Complete the **Enrollment** **CRF.** |  |  |
|  | Perform QC1 review while participant is still present, review the following for completion and accuracy:* Visit checklist and pelvic exam checklist
* **Behavioral Assessments Summary/CASI Tracking** **CRFs** for Baseline CASI
* **LDMS Specimen Tracking Sheet** and **Timed Cervical/Specimen Storage CRFs** for consistencybetween forms.
* **Medical History** and **Concomitant Medications CRFs** to ensure all conditions and medications are captured consistently
* **Enrollment CRF, Eligibility Checklist,** and **Enrollment Behavioral Eligibility Checklist**
* **Chart notes**
 |  |  |
|  | Schedule next visit* Generate participant visit calendar if not done already. Review study schedule using visit schedule tool.
* Provide any other study informational materials, site contact information, and instructions to contact the site for additional information and/or counseling if needed before the next visit: *[add site-specific list if desired]*
 |  |  |
|  | Update **Screening and Enrollment Log.**  |  |  |
|  | Provide Reimbursement |  |  |
|  | Perform QC2 review. Review participant chart contents and EDC data: Required CRFs* Vital Signs
* Physical Exam
* Pelvic Exam
* Behavioral Assessments Summary
* CASI Tracking
* STI Test Results
* HIV Test Results
* Pregnancy Test Results
* Randomization
* Timed Cervical Specimen Storage
* Specimen Storage
* Inclusion/Exclusion Criteria (Stored in the Scr Visit folder)Enrollment
* Ring Insertion and Removal
* Pregnancy Test Results

*If indicated/applicable:** Hematology
* Chemistry Panel
* Medical History (YN/Log)
* Concomitant Medications (YN/Log)
* HIV Confirmatory Test Results

Paper Forms:* Screening and Enrollment Log Form
* Enrollment Behavioral Eligibility Worksheet
* HIV Pre/Post-Test and HIV/STI Risk Reduction Counseling Worksheet
* Protocol Counseling Worksheet
* LDMS Tracking Sheet
* Pelvic Exam Diagram
* MTN-038 Study Ring Prescription (yellow copy)
* Site-Specific Clinic Study Product Accountability Log
* Eligibility Checklist
 |  |  |