| MTN-033 Enrollment Visit Checklist |
| --- |
| Procedures | Staff Initials |
|  | Confirm identity, age, and PTID |  |
|  | Confirm participant is within 30-day screening window.* WITHIN 30 days from screening visit 🡪 CONTINUE.
* OUTSIDE 30 days from screening visit 🡪 STOP. Not eligible to enroll.
 |  |
|  | Check for co-enrollment, per site SOPs:* NOT enrolled in another study 🡪 CONTINUE.
* Enrolled in another study 🡪 STOP. ASSESS ELIGIBILITY. CONSULT PSRT as needed
 |  |
|  | Review/update locator information and re-assess adequacy, per site SOPs.* Adequate locator information 🡪 CONTINUE.
* NO adequate 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 and document in chart notes:* 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 Screening Visit test results.  |  |
|  | Assess behavioral eligibility by administering **Enrollment Behavioral Eligibility Worksheet*** Eligible 🡪 CONTINUE.
* Not Eligible but likely to meet eligibility criteria within this screening attempt 🡪 PAUSE 🡪 Reschedule Enrollment Visit when participant is likely to be eligible.
* Not Eligible and Not likely to meet eligibility criteria within this screening attempt 🡪 STOP.
 |  |
|  | Administer **Baseline CASI Questionnaire**. Document administration on the **CASI Summary Y/N and CASI Tracking CRFs**.*Note: Administration of the Baseline CASI Questionnaire may occur elsewhere in the visit flow; however, administration must occur prior to randomization.* |  |
|  | Review/update baseline medical history and current medications using the **Baseline Medical History Questions Guide** to verify and/or update all information recorded at the Screening Visit. Document all updates as needed on:* **Baseline Medical History Summary/Log CRF**
* **Concomitant Medications Summary/Log CRF**
 |  |
|  | Perform a full physical exam and complete the **Vital Signs CRF** and **Physical Exam CRF**. Add relevant findings to the **Baseline Medical History Log CRF**.  |  |
|  | *If indicated*, administer pharyngeal swab for GC/CT. Complete **STI Test Results CRF** upon receipt of lab results. |  |
|  | If indicated, collect urine (15-60 mL) and perform tests:* Dipstick urinalysis and/or urine culture
* NAAT for GC/CT

Record results on **STI Test Results CRF** (if indicated). |  |
|  | 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**. |  |
|  | Collect blood samples for:* Plasma for archive \_\_\_ mL [tube type]
* HIV serology \_\_\_ mL [tube type]

Document collection of plasma archive on [specify source doc, such as visit checklist, LDMS Tracking Sheet and Specimen Storage CRF]. Enter HIV test results onto **HIV Test Results CRF** once available.If clinically indicated: * AST, ALT \_\_\_ mL [tube type]
* Syphilis serology \_\_\_\_ mL [tube type]
* Creatinine \_\_\_ mL [tube type]
* CBC with differentials and platelets \_\_\_ mL [tube type]

Enter results onto **Local Laboratory Results CRF, Hematology CRF,** and/or **STI Test Results CRF** (if indicated). |  |
|  | Provide test results and post-test counseling using HIV Pre/Post Test and Risk Reduction Counseling Worksheet; provide/document referrals if needed/requested.  |  |
|  | Perform and document genital and rectal examination using the **Genital Exam Checklist**, **Genital Exam CRF**, **Anorectal Exam CRF** and **Anorectal** **Specimen Storage CRF**. Add relevant findings to **Baseline Medical History Log CRF**. |  |
|  | Provide and explain available exam and lab test results. |  |
|  | Evaluate any abnormal findings. Explain test results and exam findings. If STI/RTI/UTI is diagnosed, provide or refer for treatment. Document provision of results, treatments and referrals in chart notes. * Symptom(s) present ⇒evaluate per site SOPs. If treatment is required ⇒ STOP. INELIGIBLE.
* No symptoms ⇒ CONTINUE.
 |  |
|  | Conduct confirmation and final determination of eligibility status by review/completion of Eligibility Checklist:* ELIGIBLE ⇒ CONTINUE. Document date and time of checklist and complete sign-off.
* NOT ELIGIBLE ⇒ STOP. Provide clinical management as needed. Document in chart notes. Enter data into study database for Eligibility Criteria CRF.
 |  |
|  | Randomize the participant. Complete the **Inclusion/Exclusion Criteria CRF** first, followed by the **Randomization CRF**. Once the participant’s randomization date and time auto-populate on the Randomization CRF, the participant is randomized. *ONCE A PARTICIPANT IS RANDOMIZED, S/HE IS OFFICIALLY ENROLLED IN THE STUDY*. |  |
|  | Provide and document protocol adherence counseling using the **Protocol Counseling Worksheet**.  |  |
|  | Perform QC1: while participant is still present, review the following:* Review Enrollment Behavioral Eligibility Worksheet, Eligibility Checklist, and chart notes to ensure completeness and accuracy
* Review LDMS Specimen Tracking Sheet to ensure completeness
* Review Baseline Medical History Log CRF, and Concomitant Medications Log CRF to ensure all conditions and medications are captured consistently
* Review Anorectal Exam, Vital Signs, and Physical Exam CRFs (or other source documents) and the Genital Exam CRF to ensure all findings are clearly documented
 |  |
|  | Update **Screening and Enrollment Log**. Generate participant visit calendar if not done already. Review study schedule using visit schedule tool. Schedule next visit and advise participant of potential length of next visit.  |  |
|  | Provide contact information and instructions to report symptoms and/or request information, additional condoms and/or counseling before next visit. |  |
|  | Provide reimbursement. |  |
|  | For enrolled participants, ensure that data is entered into the study database (and perform QC2 review, if applicable) for the following: Required CRFs: * Anorectal Exam
* Anorectal Specimen Storage
* Enrollment
* Randomization
* CASI Summary Y/N
* CASI Tracking
* Inclusion/Exclusion Criteria
* Vital Signs
* Physical Exam
* Anorectal Exam
* Genital Exam
* Specimen Storage
* HIV Test Results

As needed:* STI Test Results
* Local Laboratory Results
* Hematology

Log CRFs (complete/update as applicable) * Baseline Medical History Summary/Log
* Concomitant Medications Summary/Log
* Protocol Deviations Summary/Log

Paper Forms* Enrollment Behavioral Eligibility Worksheet
* HIV Pre/Post Test and Risk Reduction Counseling Worksheet

For failed screening attempts, the only CRF that requires completion is the Inclusion/Exclusion Criteria CRF. Other CRFs that were completed during the failed screening attempt up until the point that ineligibility was determined may remain in the study database. |  |

**Additional Notes/Comments/Referrals:**