| MTN-033 Enrollment Visit Checklist | | |
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| 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:**