**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. Use a new Screening Visit Checklist if a second screening attempt is needed.

| **Procedure** | | **Staff Initials** | **Comments:** |
| --- | --- | --- | --- |
|  | Confirm identity per site SOPs. Assess age of eligibility and proceed accordingly.   * Will be 16-21 years of age at time of enrollment ⇒ CONTINUE. * Will potentially turn 16 years old by time of enrollment (i.e., birthday within S&E window) CONTINUE. Assess eligibility to continue * Will be <16 or >21 years of age at time of enrollment ⇒ STOP. NOT ELIGIBLE. |  |  |
|  | 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.* |  |  |
|  | Determine screening attempt (Verify if MTN-034 PTID has previously been assigned)   * First attempt ⇒ Document recruitment source, CONTINUE. * Re-screen attempt ⇒ CONTINUE. |  |  |
|  | *\*For participants who are minors (16 and 17 years old)*  Explain, conduct, and document the informed assent\* process for potential participant. Complete **Informed Assent Coversheet** and **IC****comprehension Checklist**, per site SOP:   * Willing and able to provide written informed assent ⇒ CONTINUE. * NOT willing and able to provide written informed assent ⇒ STOP. NOT ELIGIBLE. * Not applicable |  |  |
|  | *\*For participants who are minors (16 and 17 years old), parental permission is required.*    Explain, conduct, and document the parental permission \* process. Complete **Informed Consent Coversheet** and **IC****comprehension Checklist**, per site SOP:   * Willing and able to provide written permission Þ CONTINUE. * NOT willing and able to provide written permission Þ STOP. NOT ELIGIBLE. * Not applicable |  |  |
|  | *\*For participants who are ≥18 yrs old.*  Explain, conduct, and document the participant informed consent\* process. Complete **Informed Consent Coversheet** and **IC****comprehension Checklist**, per site SOP:   * Willing and able to provide written informed consent ⇒ CONTINUE. * NOT willing and able to provide written informed consent ⇒ STOP. NOT ELIGIBLE. * Not applicable |  |  |
|  | Log onto the MTN-034 Medidata database and generate PTID (if not done during a previous screening attempt).  Complete new entry on **Screening and Enrollment Log** and **PTID Name Linkage Log**.  Open the Screening Visit folder to begin CRF data entry. |  |  |
|  | Explain procedures to be performed at today’s visit. |  |  |
|  | Obtain locator information and determine adequacy:   * Adequate locator information ⇒CONTINUE. * Inadequate locator information ⇒ PAUSE and re-assess:   + Adequate information likely to be available prior to enrollment ⇒ CONTINUE.   + Adequate information NOT likely to be available ⇒ STOP. NOT ELIGIBLE. |  |  |
|  | Complete **Screening Date of Visit CRF.** |  |  |
|  | Administer **Demographics CRF**. |  |  |
|  | Assess behavioral eligibility by administering the **Screening Behavioral Eligibility Worksheet**   * ELIGIBLE thus far ⇒ CONTINUE. * NOT ELIGIBLE ⇒ STOP. |  |  |
|  | Collect baseline medical, menstrual, medications history and complete:   * **Baseline Medical History Questions Form (non-CRF)** * **Screening Menstrual History CRF** * **Baseline Medical History Summary/ Log CRFs** * **Concomitant Medications Summary/ Log CRFs** |  |  |
|  | Collect mid-stream urine (15-60 mL) catch and perform tests:   * Urine hCG (pregnancy) * Dipstick urinalysis and/or culture per site SOP (if indicated) |  |  |
|  | Confirm and document pregnancy results:   * NOT pregnant ⇒ CONTINUE. * Pregnant ⇒ STOP. NOT ELIGIBLE. |  |  |
|  | Administer **Family Planning History CRF**, review study contraception requirements, and provide contraceptive counseling. Effective study methods per study protocol include:   * hormonal methods (except contraceptive ring) * intrauterine device (IUD)   [Prescribe/provide/refer for] contraception if needed; document in chart notes and/or **Contraceptive Counseling Worksheet,** and complete **Family Planning Summary/ Log CRF**,as needed. Document hormonal methods on the **Concomitant Medications Log CRF.**  *Note: Participant must be on the same contraceptive method for at least two months prior to Enrollment.* |  |  |
|  | Provide and document HIV pre-testing counseling using the **HIV Pre/Post Test and Risk Reduction Counseling Worksheet**. |  |  |
|  | Collect the following amounts of blood and send to lab for testing:   * HIV-1   + [X] mL [color] top [additive/no additive] tube * Complete blood count (CBC) with platelets   + [X] mL [color] top [additive/no additive] tube * Blood creatinine (and calculated creatinine clearance)   + [X] mL [color] top [additive/no additive] tube * Syphilis serology   + [X] mL [color] top [additive/no additive] tube * Hepatitis B surface antigen (HBsAG)   + [X] mL [color] top [additive/no additive] tube |  |  |
|  | Perform and document two rapid HIV test (s) per site SOPs. |  |  |
|  | Complete HIV test results and post-testing actions:   * Provide testing results and referrals if needed/requested per site SOPs. * If both tests negative = UNINFECTED ⇒ 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. If participant allows, collect blood and perform an HIV confirmation and refer participant to local treatment of care. * Follow Protocol HIV Testing Algorithm for follow-up actions based on confirmation test results. * Provide and document HIV post-test and HIV/STI risk reduction counseling using the **HIV Pre/Post Test and HIV/STI Risk Reduction Counseling Worksheet** * Offer condoms |  |  |
|  | Determine whether participant is positive for Hepatitis B:   * Test negative for HBsAG ⇒ CONTINUE. * Test positive for HBsAG ⇒ evaluate per site SOPs. If treatment is required ⇒ STOP. MAY BE INELIGIBLE.   Document results onto **STI Test Results CRF** when results are available.  *NOTE: If tested negative, offer HBV vaccination at the Enrollment Visit.* |  |  |
|  | Perform full physical exam and complete   * **Vital Signs CRF** * **Physical Exam CRF** |  |  |
|  | Perform and document a pelvic exam per the Pelvic Exam Checklist, including sample collection. Document on **Pelvic Exam Diagrams (non Medidata form)** and **Pelvic Exam CRF.** |  |  |
|  | Determine whether participant has current RTI/STI/UTI/PID symptoms and document provision of results:   * No symptoms ⇒ CONTINUE. * Symptom(s) present ⇒ evaluate per site SOPs. If treatment is required ⇒ STOP. May be INELIGIBLE. Provide any clinically indicated treatment and/or referrals   Document provision of results, treatment and/or referrals in chart notes.  *NOTE: If participant is symptomatic and is diagnosed with an RTI/STI/UTI/PID, she must complete treatment and all symptoms must resolve before she is eligible for enrollment. Treat if indicated per site SOP.* |  |  |
|  | Evaluate findings identified during pelvic and physical examinations and medical and menstrual history review. Document in chart notes and update **Concomitant Medications Log** **CRF**, if applicable. Document ongoing conditions on the **Baseline** **Medical History Log** **CRF**.  Provide and explain all available findings and results. Refer for other findings as indicated. |  |  |
|  | Assess participant’s current eligibility status:   * ELIGIBLE thus far ⇒ CONTINUE. * NOT ELIGIBLE but likely to meet eligibility criteria within this screening attempt ⇒ PAUSE. Perform and document relevant outcomes of all clinically indicated procedures. 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 clinical management and referrals as needed. |  |  |
|  | Perform QC1 review while participant is still present, review the following for completion and clear documentation:   * **Screening Behavioral Eligibility Worksheet** to ensure all items are complete * **Demographics CRF, Screening Menstrual History CRF, Pelvic Exam Diagrams, Pelvic Exam CRF, Vital Signs CRF,** and **Physical Exam CRF** to ensure all findings are clearly documented. * **Baseline Medical History Questions, Baseline Medical History Log, Family Planning History, Family Planning Log,** and **Concomitant Medications Log** to ensure all conditions and medications are captured consistently. * **Chart notes** to ensure complete and accurate. |  |  |
|  | Provide study informational material (e.g., factsheets), 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]* |  |  |
|  | Determine last possible enrollment date for this screening attempt using the **Visit Calendar Tool, Last Day to Enroll.\***    DD MON YY  Schedule next visit and advise her of potential length of next visit.  *\*Enrollment visit should be no greater than 70 days from Screening, and, no less than 60 days from the day a new contraceptive method is initiated.* |  |  |
|  | Provide Reimbursement |  |  |
|  | If participant will proceed to the Enrollment Visit, leave **Eligibility Checklist** blank and complete form at Enrollment Visit along with the **Eligibility Criteria CRF**.  If participant will not proceed to the Enrollment Visit, complete **Eligibility Checklist.** Complete and submit **Eligibility Criteria CRF.** Other CRFs that were completed during the failed screening attempt may remain in the study database, and will not undergo QC review. |  |  |
|  | Perform QC2 review. Review participant chart contents and EDC data:  Required CRFs   * Eligibility Criteria (completed at Screening if participant is ineligible) * Demographics * Local Laboratory Results * Baseline Medical History Summary * Concomitant Medications Summary * Family Planning History * Family Planning Summary * Pelvic Exam * Physical Exam * Screening Date of Visit * Screening Menstrual History * Vital Signs * STI Test Results   *As needed*   * Concomitant Medications Log (if medications are reported) * Family Planning Log (if FP methods are reported) * Baseline Medical History Log (if pre-existing conditions are reported)   Paper Forms/Tools:   * Informed Consent/Assent Coversheet * Informed Consent Comprehension Assessment * PTID Name Linkage Log * Screening and Enrollment Log Form * Screening Behavioral Eligibility Worksheet * Baseline Medical History Questions Form * HIV Pre/Post-Test and HIV/STI Risk Reduction Counseling Worksheet * Pelvic Exam Diagrams * Safety Lab Calculator * Eligibility Checklist, *if applicable* * Visit Calendar Tool, Last Day to Enroll |  |  |