**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
 |  |  |