**Instructions:** Complete staff initials next to procedures completed. 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 and age per site SOPs. * Will be 18-40 years of age at time of enrollment 🡪CONTINUE.
* Will potentially turn 18 years old by time of enrollment (i.e., birthday within S&E window) 🡪 CONTINUE. Assess eligibility to continue
* Will be <18 or >40 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.
 |  |  |
|  | Explain, conduct, and document the mother informed consent process for potential participant. Complete **Informed Consent Coversheet** and **Mother IC****comprehension Assessment**, per site SOP. * Provide information regarding Cohort 1 safety outcomes per IRP review

Complete/review MTN-042/MTN-043 Study Enrollment Decision Tool with mother before she signs the ICF.* Willing and able to provide written informed consent 🡪 CONTINUE.
* NOT willing and able to provide written informed consent 🡪 STOP. NOT ELIGIBLE.
 |  |  |
|  | [Sites to include if Infant IC will be administered at Mother’s screening visit:] Explain, conduct, and document the infant informed consent process. Complete **Informed Consent Coversheet** and **Infant IC****comprehension Assessment**, per site SOP. * Willing and able to provide written informed consent for infant 🡪CONTINUE.
* NOT willing and able to provide written informed consent for infant 🡪 STOP. NOT ELIGIBLE.

*NOTE:. Wait until live birth is confirmed to consider infant ‘enrolled’* |  |  |
|  | [Sites to include if Infant IC is not completed at this visit]: Confirm that the participant intends and is willing to enroll her infant :* Yes, the participant intends to and is willing to provide IC for their infant 🡪CONTINUE.
* No, the participant does not intend to or is not willing to provide IC for their infant 🡪 STOP. NOT ELIGIBLE.
 |  |  |
|  | **MOTHER** Completing **Participant Identifier CRF,** and **Participant Type CRF** and **Informed Consent CRF.**Complete new entry on **Screening and Enrollment Log** and **PTID Name Linkage Log**.  |  |  |
|  | **INFANT**: Generate infant PTID and complete **Participant Identifier CRF, Participant Type CRF** and **Informed Consent CRF**.Complete appropriate column on **Screening and Enrollment Log** and **PTID Name Linkage Log** for infant (beside the Mother’s entry).Return to the mother’s **Participant Type CRF** and enter the infant’s PTID. |  |  |
|  | Determine screening attempt (Verify if MTN-042 PTID has previously been assigned)* First attempt 🡪 Document recruitment source per site SOPs, CONTINUE.
* Re-screen attempt (note: only 1 rescreen is allowed) 🡪 CONTINUE.

Complete **Screening Date of Visit CRF.** *Note: visit date is the first day of a split visit, if applicable.* |  |  |
|  | 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.
 |  |  |
|  | Administer **Demographics CRF**. |  |  |
|  | Assess behavioral eligibility by administering the **Screening Behavioral Eligibility Worksheet** * ELIGIBLE thus far 🡪 CONTINUE.
* NOT ELIGIBLE 🡪 STOP.
 |  |  |
|  | Obtain written authorization for site to contact participant’s antenatal and postpartum care provider(s) and to obtain copies of antenatal and postpartum care records, per site SOP. |  |  |
|  | Verify the delivery facility/hospital that the participant plans to deliver at and document on [site-specific form]. |  |  |
|  | Collect baseline medical, obstetric, medications (including medicated vaginal products) history using the Baseline Medical and Obstetric History Question Guide and review any available antenatal care records and complete:* **Baseline Medical History Y/N and Log CRFs**
* **Concomitant Medications Y/N and Log CRFs, if applicable**
* **Relevant source documents**
 |  |  |
|  | Complete **Pregnancy History CRF.** |  |  |
|  | Complete **Vaginal Practices CRF.** Provide counseling on healthy vaginal practices/hygiene per standard of care, as needed*Note: all medicated vaginal products (including prescription medications, over-the-counter preparations, vitamins and nutritional supplements, and herbal preparations which are intended to function as medication) should be recorded on the* ***Concomitant Medications Log.*** |  |  |
|  | Confirm if participant has available, valid ultrasound results [see SSP section 7.7 for required U/S elements for eligibility determination]* YES 🡪 obtain/review results and complete **Ultrasound Results CRF** (Note: CRF is in Visit 2 - Enrollment Visit folder)
* NO 🡪 schedule (or perform) ultrasound

*NOTE: Ultrasound results from ≤28 weeks gestation must be available to be eligible for enrollment*  |  |  |
|  | Calculate gestational age using all available information (e.g. LMP, and ultrasound results, if available). Use following online tool to calculate gestational age based on LMP: <http://perinatology.com/calculators/Due-Date.htm> A gestational age redating tool is available on the MTN website.Confirm potential eligibility within screening window:* Will likely be within cohort gestational range at time of enrollment 🡪 CONTINUE.
* Will be less than 36 weeks in the next 35 days 🡪STOP. Not eligible to enroll during this screening attempt 🡪 If willing, schedule for rescreening.
* Past cohort gestational range 🡪 STOP INELIGIBLE

*NOTE: Gestational age range for Cohort 2 enrollment is* ***30 0/7 weeks – 35 6/7 weeks.*** |  |  |
|  | Collect urine (15-60 mL) and perform tests:* Dipstick urinalysis
* Culture per site SOP

Document on **Urine Test Results CRF.** |  |  |
|  | Provide self-collected swab instructions and have participant collect 1 swab for NAAT for GC/CT/Trich.  |  |  |
|  | 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] tube
* Complete blood count (CBC) with platelets
	+ [X] mL [color] top [additive] tube
* AST/ALT
	+ [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 and complete HIV test results and post-testing actions (including 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. Per standard of care and if participant allows, collect blood and perform an HIV confirmation and refer participant to local treatment of care.
 |  |  |
|  | * 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
 |  |  |
|  | Perform full physical exam and complete **Vital Signs CRF** and **Physical Examination CRF**  |  |  |
|  | Perform obstetric abdominal exam and complete **Obstetric abdominal Exam CRF***.* |  |  |
|  | Determine whether participant has current RTI/STI/UTI/cervicitis symptoms:* 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.
 |  |  |
|  | *If indicated,* perform and document a pelvic exam per the *Pelvic Exam Checklist*. * N/A
 |  |  |
|  | Evaluate findings identified during obstetric, physical, pelvic (*if indicated*) examinations, medical and pregnancy history, and antenatal care record 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**
* **Demographics CRF**
* **Obstetric abdominal Exam CRF, Vital Signs CRF,** and **Physical Examination CRF**
* **Baseline Medical History Log, Pregnancy History, Vaginal Practices,** and **Concomitant Medications Log** **CRF**s to ensure all conditions and medications are captured consistently.
* **Chart notes**. Refer to QC Schedule Reference Tool as needed.
 |  |  |
|  | 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 **Cohort 2 Visit Calendar Tool, Last Day to Enroll.\*** Print and filecompleted tool in participant binder. Schedule next visit and advise her of potential length of next visit.  |  |  |
|  | Provide Reimbursement |  |  |
|  | If participant will proceed to the Enrollment Visit, leave the Eligibility Checklist blank and complete at Enrollment Visit along with the Inclusion/Exclusion Criteria CRF.If participant will not proceed to the Enrollment Visit, complete and submit the **Inclusion/Exclusion Criteria CRF.** Other CRFs that were completed during the failed screening attempt may remain in the study database, and will not undergo QC review. If infant PTID has been assigned, complete the **Infant Inclusion/Exclusion CRF** to indicate the infant will not enroll. |  |  |
|  | Perform QC2 review. Review participant chart contents and EDC data: Required CRFs* Screening Date of Visit
* Informed Consent
* Inclusion/Exclusion Criteria (complete at Screening if participant is ineligible)
* Demographics
* Hematology\*
* Chemistry Panel\*
* Pregnancy History
* Obstetric abdominal Exam
* Vaginal Practices
* Physical Examination
* Screening Date of Visit
* Vital Signs
* STI Test Results\*
* Urine Test Results

*As needed** Pelvic Exam
* Ultrasound Results *(located in Enrollment Visit folder)*
* Concomitant Medications YN/Log (if medications are reported)
* Baseline Medical History YN/Log (if pre-existing conditions are reported)

Paper Forms/Tools:* Informed Consent Coversheet (for each the mother and infant)
* Mother Informed Consent Comprehension Assessment
* Infant Informed Consent Comprehension Assessment
* MTN-042/MTN-043 Study Enrollment Decision Tool
* PTID Name Linkage Log
* Screening and Enrollment Log
* Screening Behavioral Eligibility Worksheet
* HIV Pre/Post-Test and HIV/STI Risk Reduction Counseling Worksheet
* Pelvic Exam Diagrams, *as applicable*
* Cohort 2 Visit Calendar Tool, Last Day to Enroll

*\*CRFs/Tools to be completed when lab results are available* |  |  |