**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 **MOTHER** identity and age per site SOPs. * Will be ≥ 18 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 years of age at time of enrollment🡪 STOP. NOT ELIGIBLE.
 |  |  |
|  | Confirm **INFANT** identity and age per site SOPs. * Will be 6-12 weeks of age (inclusive) at time of enrollment 🡪CONTINUE.
* Will potentially be 6-12 weeks of age (inclusive) by time of enrollment (i.e., turns 6-weeks within S&E window) 🡪 CONTINUE. Assess eligibility to continue.
* Will be < 6 weeks or >12 weeks 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 informed consent process for potential participants. Complete **Informed Consent Coversheet** and **IC****comprehension Assessment**, per site SOP. 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.
 |  |  |
|  | Completing **Participant Identifier CRF and Participant Type CRF** and **Informed Consent CRF** for **MOTHER** and **INFANT.**Complete new entry on **Screening and Enrollment Log** and **PTID Name Linkage Log**  |  |  |
|  | Determine screening attempt (Verify if MTN-043 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** for **MOTHER** and **INFANT.***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** for **MOTHER** and **Infant** **Demographics CRF** for **INFANT.** |  |  |
|  | Assess behavioral eligibility by administering the **Screening Behavioral Eligibility Worksheet.** * ELIGIBLE thus far 🡪 CONTINUE.
* NOT ELIGIBLE 🡪 STOP.
 |  |  |
|  | Obtain written authorization from mother for site to contact the infant’s pediatric care provider(s) and to obtain copies of medical records, per site SOP. |  |  |
|  | **MOTHER**: Collect urine (15-60 mL) and perform tests:* Pregnancy
* Dipstick urinalysis and/or culture per site SOP***, if indicated***
	+ N/A

Document on **Urine Test Results CRF***, if indicated* |  |  |
|  | Provide and document HIV pre-testing counseling using the **HIV Pre/Post Test and Risk Reduction Counseling Worksheet**. |  |  |
|  | **MOTHER**: 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
 |  |  |
|  | **MOTHER**: Review study contraception requirements, and provide contraceptive counseling. Effective study methods per study protocol include: * hormonal methods (except contraceptive ring)
* intrauterine device (IUD)
* surgical sterilization

[Prescribe/provide/refer for] contraception if needed; document in chart notes and/or **Contraceptive Counseling Worksheet.** Document hormonal methods/IUDs on the **Concomitant Medications Log CRF.** |  |  |
|  | **MOTHER**: Administer the **Feeding Assessment – Screening and Enrollment CRF**.* ELIGIBLE thus far 🡪 CONTINUE.
* NOT ELIGIBLE 🡪 STOP.
 |  |  |
|  | Collect **MOTHER** baseline medical, medications (including medicated vaginal products) history using the Mother Baseline Medical History Question Guide. Collect **INFANT** baseline medical, medications history using Infant Baseline Medical History Guide and review any available pediatric care records for the infant. Complete**:*** **Baseline Medical History Y/N and Log CRFs** for **MOTHER** and **INFANT**
* **Concomitant Medications Y/N and Log CRFs, if applicable** for **MOTHER** and **INFANT**
* **Relevant source documents**
 |  |  |
|  | **MOTHER**: Complete **Pregnancy History CRF.** |  |  |
|  | **MOTHER**: 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.*** |  |  |
|  | **MOTHER**: Perform full physical exam and complete **Vital Signs CRF** and **Physical Examination CRF**  |  |  |
|  | **MOTHER**: Perform and document a pelvic exam and collect pelvic samples per the *Pelvic Exam Checklist*. Document on **Pelvic Exam Diagrams** and **Pelvic 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.
 |  |  |
|  | **INFANT:** Perform full physical exam including weight and complete **Infant Vital Signs CRF** and **Physical Examination CRF** |  |  |
|  | Administer the appropriate **Ages and Stages Questionnaire** and complete **Infant Ages and Stages Assessment CRF** for **INFANT** |  |  |
|  | Evaluate findings identified during physical, pelvic examinations, medical and pregnancy history, and pediatric care record review. Document in chart notes and update **MOTHER** and **INFANT Concomitant Medications Log** **CRF**, if applicable. Document ongoing conditions on the **Baseline** **Medical History Log** **CRF** for **MOTHER** and **INFANT**Provide and explain all available findings and results. Refer for other findings as indicated. |  |  |
|  | Assess participants; (Mother and Infant) 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:**MOTHER**:* **Screening Behavioral Eligibility Worksheet**
* **Demographics CRF**
* **Pelvic Exam, 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.
* **Feeding Assessment/Inventory CRFs**
* **Chart notes**.

**INFANT*** **Infant Demographics CRF**
* **Infant Vital Signs CRF,** and **Physical Examination CRF**
* **Baseline Medical History Log,** and **Concomitant Medications Log** **CRF**s to ensure all conditions and medications are captured consistently.
* **Infant Ages and Stages Assessment**
* **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 **Visit Calendar Tool, and Last Day to Enroll Calculator.**  Print and filecompleted tool in participant binder. Schedule next visit and advise her of potential length of next visit.  |  |  |
|  | Provide Reimbursement |  |  |
|  | If participants will proceed to the Enrollment Visit, leave the Eligibility Checklist blank and complete at Enrollment Visit along with the Inclusion/Exclusion Criteria CRFs.If participants will not proceed to the Enrollment Visit, complete and submit the **Inclusion/Exclusion Criteria CRF** and **Infant 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. |  |  |
|  | Perform QC2 review. Review participant chart contents and EDC data: **MOTHER**:Required CRFs* Screening Date of Visit
* Informed Consent
* Inclusion/Exclusion Criteria (complete at Screening if participant is ineligible)
* Demographics
* Hematology\*
* Chemistry Panel\*
* Pregnancy History
* Vaginal Practices
* Feeding Assessment – Screening and Enrollment
* Pelvic Exam
* Physical Examination
* Vital Signs
* STI Test Results\*

*As needed** Concomitant Medications YN/Log (if medications are reported)
* Baseline Medical History YN/Log (if pre-existing conditions are reported)
* Urine Test Results\*

Paper Forms/Tools:* Informed Consent Coversheet
* 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
* Contraceptive Counseling Worksheet
* Pelvic Exam Diagrams
* Visit Calendar Tool, Last Day to Enroll Calculator

**INFANT**Required CRFs* Screening Date of Visit
* Informed Consent
* Infant Inclusion/Exclusion Criteria (complete at Screening if participant is ineligible)
* Infant Demographics
* Physical Examination
* Infant Vital Signs
* Infant Ages and Stages Assessment

*As needed** Concomitant Medications YN/Log (if medications are reported)
* Baseline Medical History YN/Log (if pre-existing conditions are reported)

Paper form: * Ages and Stages Questionnaire

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