**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* |  |  |