**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.

| **Procedure** | **Staff Initials** | **Comments:** |
| --- | --- | --- |
|  | Confirm identity and PTID of **MOTHER** and **INFANT** |  |  |
|  | Check for co-enrollment in other studies per site SOPs for **MOTHER** and **INFANT**:* NOT enrolled in another study ⇒ CONTINUE.
* Enrolled in another study ⇒ STOP. Consult the PSRT regarding safety considerations.
 |  |  |
|  | Review elements of informed consents as needed. Explain procedures to be performed at today’s visit for mother and infant. |  |  |
|  | Review/update locator information using site-specific form for **MOTHER** and **INFANT.** |  |  |
|  | Provide available test results from previous visit for **MOTHER** and **INFANT.** Treat and/or refer for care as required. |  |  |
|  | Complete the **Follow-up Visit Y/N CRF** (within each the **MOTHER** and **INFANT** folder) |  |  |
|  | **MOTHER:** Have participant self-collect 5 swabs for:* NAAT for GC/CT/Trich (local lab)
* Microbiota analysis – qPCR (MTN LC)
* pH assessment (local lab)
* Gram stain (MTN LC) – *note: can be done from pH swab*
	+ Roll swab across two labeled slides and air dry.
* Biomarker analysis (MTN LC)

*NOTE: Refer to self-collection instructions sheet as needed. May be done by clinician, if preferred by participant. If pelvic exam is done during the visit, collect all swabs during the exam.* |  |  |
|  | **MOTHER:** Offer pregnancy test. Collect urine (15-60 mL) and perform tests:* Dipstick urinalysis
* Culture per site SOP
* Pregnancy (optional)
	+ N/A *(declined test)*

Document on **Urine Test Results CRF.** |  |  |
|  | Collect/review delivery, well-baby care records including for infant health, anthropometry, feeding history; and review mother medical/obstetric/medications (including medicated vaginal products) history, and postpartum care records.* **MOTHER:** document findings, including any AEs on **Adverse Event Y/N and Log CRFs, Non-enrolled Infant Adverse Event Y/N and Log CRFs** [for any newly reported AEs on non-enrolled infant], and **Concomitant Medications Log CRF,** as needed.
 |  |  |
| * **INFANT:** Complete **Infant Feeding Assessment CRF**. Document any infant medical conditions and/or medications on the **Adverse Event Y/N and Log** and **Concomitant Medications Log CRFs (**infant folder), as needed.
 |  |  |
|  | Since her last visit, has the participant inserted anything in her vagina? Please include non-medicated gels, water, soap, dry materials (such as paper, ashes, or powders), and any other materials inserted vaginally. If yes, complete a **Vaginal Practices CRF**.*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.*** |  |  |
|  | Administer **COVID Behavioral Assessment CRF** |  |  |
|  | **MOTHER:** Administer the **Social Benefits CRF** and **Social Impact CRF** and complete **Social Impact Y/N and Log CRFs**, as applicable. |  |  |
|  | **MOTHER:** Administer **Edinburgh Postnatal Depression Scale CRF.** Refer for counseling/support, if needed. If after further clinical assessment, diagnosis of depression and/or other mental health conditions are made, record on the **Adverse Event Log.** |  |  |
|  | **MOTHER:** Provide contraceptive counseling and prescribe contraceptives as necessary. Document in chart notes and/or on **Contraceptive Counseling Worksheet.** |  |  |
|  | **MOTHER:** Administer and document HIV pre-testing and HIV/STI risk reduction counseling using the **HIV Pre/Post Test and HIV/STI 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
* AST/ALT
	+ [X] mL [color] top [additive/no additive] tube
* Syphilis serology
	+ [X] mL [color] top [additive/no additive] tube
* Complete blood count (CBC) with platelets
	+ [X] mL [color] top [additive] tube
* Blood creatinine (and calculated creatinine clearance) [weight must be taken for CrCl calculation]
	+ [X] mL [color] top [additive/no additive] tube
 |  |  |
|  | **MOTHER:**Perform and document two rapid HIV test(s) per site SOPs and complete HIV test results and post-testing actions (referrals if needed/requested per site SOPs):* If both tests negative = UNINFECTED 🡪 CONTINUE.
* If both tests positive = INFECTED 🡪STOP ***or****,*
* If one test positive and one test negative = DISCORDANT 🡪 STOP. (Refer to MTN-042 HIV Confirmation and Seroconversion Procedure Guide for complete instructions.)

Document test results onto **HIV Test Results CRF** and **HIV Confirmatory Results CRF**, if applicable. |  |  |
|  | **MOTHER:*** Provide and document HIV post-test counseling using the **HIV Pre/Post Test and HIV/STI Risk Reduction Counseling Worksheet\*\***
* Offer condoms
 |  |  |
|  | **INFANT:** Collect the following amounts of blood and send to lab for testing:* Blood creatinine
	+ [1] mL [color] top [additive/no additive] tube

***If indicated**** HIV-1
	+ [X] mL [color] top [additive] tube
* AST/ALT
	+ [X] mL [color] top [additive/no additive] tube
* Complete blood count (CBC) with platelets
	+ [X] mL [color] top [additive] tube
 |  |  |
|  | **INFANT:** ***If indicated,\*\**** perform and document HIV testing per local standard of care:* If test (s) negative = UNINFECTED ==> CONTINUE.
* If test (s) positive = INFECTED ==> STOP ***or****,*

If one test positive and one test negative = DISCORDANT ==> STOP. Contact the MTN Virology Group Urgently for Guidance. Conduct any locally required standard of care as needed while Virology feedback pending Document test results onto **Infant HIV Confirmatory Results CRF**, if applicable.*\*\*HIV testing must be performed on an infant born to an HIV infected mother* |  |  |
|  | **MOTHER:** ***If indicated,*** perform and document targeted physical exam. Complete **Vital Signs CRF** and **Physical Examination CRF**. |  |  |
|  | **INFANT:** Perform and document targeted physical exam. Complete **Infant Vital Signs CRF** and **Physical Examination CRF** *(infant folder).* Plot infant weigh, length and head circumference on appropriate growth chart.  |  |  |
|  | **MOTHER:** ***If indicated****,* perform and document a pelvic exam per the Pelvic Exam Checklist. Document on **Pelvic Exam Diagrams** and **Pelvic Exam CRF.** |  |  |
|  | Evaluate findings identified during physical examinations and medical history review for **MOTHER** and **INFANT**. Document in chart notes and update **Concomitant Medications Log, AE Y/N and Log** **CRFs**, if applicable, and document ongoing conditions on **AE Log** *(in respective mother and infant folders).* |  |  |
|  | Provide and explain all available findings and results of infant and herself to participant. Refer for other findings as indicated. ***If indicated****,* treat for STI/RTI/UTI per site SOP. |  |  |
|  |  **MOTHER:** Provide protocol adherence counseling using the *MTN-042 Protocol Adherence Counseling Guide.* Document any questions or issues on this checklist or in chart notes. |  |  |
|  | **MOTHER:**  Complete **Study Termination CRF** |  |  |
|  | **MOTHER:**  Complete **Maternal Study Exit Worksheet** and Permission to Contact Log [and or sites specific tool]. As indicated per protocol, arrange future contact for follow-up on ongoing AEs.  |  |  |
|  | Complete the* **MOTHER: Follow-up Visit Summary CRF**
* **INFANT: Infant Follow-up Visit Summary CRF**
 |  |  |
|  | Perform QC1: while participant is still present, review the following for completion and clear documentation:**Mother:*** **LDMS Specimen Tracking Sheet**, **Specimen Storage CRF**
* **AE Logs** and **Concomitant Medications Logs** to ensure all conditions, medications, AEs are captured consistently and updated.
* **Chart notes**
* **HIV results, Urine Test Results CRFs**
* **Social Impact CRF, Social Benefits CRF and Social Impact Log CRF**

**Infant:*** **AE Logs** and **Concomitant Medications Logs** to ensure all conditions, medications, AEs are captured consistently and updated.
* **Chart notes**
* **Physical Examination, Infant Vital Signs CRFs**
 |  |  |
|  | Schedule next visit for infant (6-month Visit) and, if indicated, for mother.* Provide contact information and instructions to report and/or request information, counseling, or condoms before next visit.
* Offer condoms if not already done.
 |  |  |
|  | Provide reimbursement. |  |  |
|  | Perform QC2 review and ensure that data is entered in Medidata for the following CRFs/forms:**MOTHER**Required CRFs* Follow-up Visit Y/N
* Follow-up Visit Summary
* HIV Test Result
* STI Test Results\*
* Hematology Results \*
* Chemistry Panel\*
* Specimen Storage
* Urine Test Results
* Study Termination
* Social Benefits
* Social Impacts
* COVID Behavioral Assessment CRF

*As needed* * HIV Confirmatory Results
* Adverse Events Log
* Concomitant Medications Log
* Social Impact Log
* Vital Signs
* Physical Exam
* Pelvic Exam

*\*CRFs/Tools to be completed when lab results are available*Paper Forms:* LDMS Specimen Tracking Sheet
* HIV Pre-/Post-Test and HIV/STI Risk Counseling Worksheet
* Contraceptive Counseling Worksheet
* Study Exit Worksheet

*If indicated/applicable* * Pelvic Exam Diagram
 |  |  |
|  | **INFANT**Required CRFs* Follow-up Visit Y/N
* Follow-up Visit Summary- Infant
* Vital Signs- Infant
* Physical Exam
* Chemistry Panel
* Infant Feeding Assessment

*As needed* * HIV Confirmatory Results -Infant
* Adverse Events Log
* Concomitant Medications Log
* Hematology Results\*
* Congenital Anomaly Review
* Photographic Survey
* EAE Upload

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