**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.** |  |  |
|  | Check for co-enrollment in other studies per site SOPs:* NOT enrolled in another study ⇒ CONTINUE.
* Enrolled in another study ⇒ STOP. Consult the PSRT regarding on-going safety considerations.
 |  |  |
|  | Review elements of informed consent(s) as needed. Explain procedures to be performed at today’s visit for mother and infant. |  |  |
|  | Confirm Mother’s consent for infant to continue in study today:* Consent for infant confirmed 🡪CONTINUE.
* Consent for infant withdrawn🡪 STOP. INFANT NOT ELIGIBLE TO CONTINUE. Complete the infant’s Study Termination CRF if the pregnancy outcome was a live birth.

**OR:*** Pregnancy outcome did not result in a live birth (infant not considered enrolled). Update Screening and Enrollment Log, Infant Inclusion/Exclusion CRF, and Participant Type CRF accordingly. Provide supportive grief counseling and/or referrals to mother.
 |  |  |
|  | 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. INFANT IS NOW ENROLLED IN THE STUDY.
* NOT willing and able to provide written informed consent for infant 🡪 STOP. DO NOT CONDUCT ANY INFANT PROCEDURES/CRFs. DO NOT ASSIGN INFANT PTID. Continue with material visit procedures, if agreed to by participant and notify MTN-042 management team.
 |  |  |
|  | Complete the **Infant Inclusion/Exclusion CRF** to indicate infant enrolled (i.e., consent was provided and infant was born alive). |  |  |
|  | Review/update locator information using site-specific form for **MOTHER** and **INFANT.** |  |  |
|  | Confirm facility name where participant delivered. Review/update signed medical records release and delivery care provider information. |  |  |
|  | Provide available test results from previous visit. Treat and/or refer for care as required. |  |  |
|  | Generate infant PTID and complete **Participant Identifier CRF, Participant Type CRF** and **Informed Consent CRF** for **INFANT**.Complete appropriate column on **Screening and Enrollment Log** and **PTID Name Linkage Log** for infant (beside the Mother’s entry).  |  |  |
|  | Complete the **Follow-up Visit Y/N CRF** (within each the **MOTHER** and **INFANT** casebook) |  |  |
|  | Collect study all study product still in participant’s possession as applicable:* N/A, no product returned at this visit*.*

**For ring users:** Collect used ring, send to lab for storage, and document on **Participant-Specific Clinic Study Product Accountability Log, Specimen Storage CRF**, and **Ring Insertion and Removal CRF.****If pill users:** Collect study pill bottle with any unused pills and send back to pharmacy, if applicable. Document on **Participant-Specific Clinic Study Product Accountability Log** and **PrEP Provisions and Returns CRF.***Note: Product returned between time of removal for delivery and the PPO visit should be documented as an interim visit.*  |  |  |
|  | Complete **Study Product Request Slip** by marking “Product Use Complete” and send to pharmacy. Complete **Discontinuation of Study Product CRF.***Note: Not required if product was returned by the participant or delivery facility at an interim visit prior to this visit.* |  |  |
|  | **MOTHER:** ***If indicated,*** collect mid-stream urine (15-60 mL) catch and perform tests:* Dipstick urinalysis
* Culture per site SOP

Document on **Urine Test Results CRF.** |  |  |
|  | Collect/review delivery and postpartum care records including for infant health, anthropometry, feeding history; and review mother medical, medications (including medicated vaginal products), and obstetric history.* Complete **Pregnancy Outcome CRF** *(mother casebook).*
* **MOTHER:** document findings, including any AEs on **Adverse Event Y/N and Log CRFs (include any fetal AEs prior to birth\*),** and **Concomitant Medications Log CRF,** as needed.
* **INFANT:** Complete **Infant Feeding Assessment CRF**. Document any newly identified infant medical conditions (post-birth) and/or medications on the **Adverse Event Y/N and Log** and **Concomitant Medications Log CRFs (**infant casebook), as needed.

\* For any congenital anomalies identified on ultrasound, DO NOT report an AE in the maternal casebook. Instead chart note and evaluate after the infant is born to determine if the condition should be reported on the Infant AE Log.NOTE: For an infant enrolled at this visit (i.e. not enrolled at time of birth), transfer all entries from the **Non-enrolled Infant AE Log** (mother casebook) to the **AE Log** in the Infant casebook. Fetal AEs should remain in the maternal casebook and be resolved upon pregnancy outcome. Deactivate all entries in the Non-enrolled Infant AE Log. Follow all new or transferred AEs on the infant’s AE Log to resolution.  |  |  |
|  | 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.*** |  |  |
|  | ***If indicated,*** take photo(s) of the infant to document any congenital abnormalities. Save photos as part of the infant source record and document on **Pregnancy Outcome CRF** and in chart notes. Add a Congenital Anomaly Review folder to the infant’s casebook and complete the **Congenital Anomaly Review CRF** and upload photos to the **Photographic Survey CRF**. As needed, complete **EAE Upload CRF**. |  |  |
|  | Complete **Infant Demographics CRF** |  |  |
|  | ***If indicated,*** provide contraceptive counseling to discuss what methods the participant may want to initiate at her 6-week PPO visit. Document in chart notes and/or on **Contraceptive Counseling Worksheet.** |  |  |
|  | **MOTHER:** ***If indicated,*** 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:* Plasma for DPV
* *N/A for Truvada user*
	+ 5 mL Purple top (EDTA) tube
* Dried blood spot (DBS) for PK
* *N/A for ring user*
	+ 4 mL Purple top (EDTA) tube

***If indicated**** 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 CCR calculation]
	+ [X] mL [color] top [additive/no additive] tube

Document stored specimen collection on the **Specimen Storage CRF** *(mother casebook)* and **LDMS Specimen Tracking Sheet.** |  |  |
|  | **MOTHER: *If indicated,*** 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 ***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 Result CRF** and **HIV Confirmatory Results CRF**, if applicable. |  |  |
|  | **MOTHER: *If indicated**** 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:* Plasma for DPV
* *N/A born to mother in Truvada group*
	+ 2 mL Purple top (EDTA) tube
* Dried blood spot (DBS) for PK (UTC Lab)
* *N/A born to mother in ring group*
	+ 1 mL Purple top (no additive) tube
* Blood creatinine
* N/A *born to mother in ring group*
	+ [X] 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

Document stored specimen collection on the **Infant Specimen Storage CRF** *(infant casebook)*and **LDMS Specimen Tracking Sheet.** |  |  |
|  | **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:** Perform and document targeted physical exam. Complete **Vital Signs CRF** and **Physical Examination CRF**. |  |  |
|  | **INFANT:** Perform and document full physical exam. Complete **Infant Vital Signs CRF** and **Physical Exam CRF***.* Plot infant weigh, length and head circumference from birth and from physical exam completed at this visit on appropriate growth chart.  |  |  |
|  | 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 casebooks).* |  |  |
|  | 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. |  |  |
|  | Provide protocol adherence counseling using the *MTN-042 Protocol Adherence Counseling Guide*. Document any questions or issues on this checklist or in chart notes. |  |  |
|  | Complete:* **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**
* **Pregnancy Outcome, AE Logs. Non-Enrolled Infant AE Log, and Concomitant Medications Logs** to ensure all conditions, medications, AEs are captured consistently and updated.
* **Participant-Specific Clinic Study Product Accountability Log** and **Ring Insertion and Removal** or **PrEP Provisions and Returns CRF,** and **Discontinuation of Study Product CRF** are consistently completed, if needed.
* **Chart notes**
* **Physical Examination and Vital Signs CRFs**

**Infant:*** **LDMS Specimen Tracking Sheet**, **Infant Specimen Storage CRF**
* **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 (6-week PPO) * Generate the mother and infant’s remaining visit schedule using the Visit Calendar Tool by entering the mother’s PO date on the Mother and Infant sheets. Print, sign, and file the sheets in the respective PTID binder.
* Provide contact information and instructions to report symptoms and/or request information, counseling, or condoms before next visit.
* Offer condoms if not already done.
 |  |  |
|  | Provide reimbursement for **MOTHER** and **INFANT** per site SOP. |  |  |
|  | 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
* Specimen Storage
* Vital Signs
* Physical Examination
* Pregnancy Outcome

*As needed* * Ring Insertion and Removal, or PrEP Provisions and Returns *(per participant’s study arm)*
* Discontinuation of Study Product
* HIV Test Result
* HIV Confirmatory Results
* Adverse Events Log
* Non-enrolled Infant Adverse Events Log
* Concomitant Medications Log
* STI Test Results\*
* Hematology Results \*
* Chemistry Panel\*
* IDI Tracking

*\*CRFs/Tools to be completed when lab results are available*Paper Forms:* LDMS Specimen Tracking Sheet

*If indicated/applicable* * Study Product Request Slip
* Participant-Specific Clinic Study Product Accountability Log
* Qualitative Participation Log (QPL)
* HIV Pre-/Post-Test and HIV/STI Risk Counseling Worksheet
* Contraceptive Counseling Worksheet
 |  |  |
|  | **INFANT**Required CRFs* Follow-up Visit Y/N
* Informed Consent
* Infant Follow-up Visit Summary
* Infant Specimen Storage
* Infant Vital Signs
* Infant Demographics
* Physical Exam
* Chemistry Panel
* Infant Feeding Assessment

*As needed* * Infant HIV Confirmatory Results
* 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* |  |  |