**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 infant |  |  |
|  | Check for co-enrollment in other studies per site SOPs for infant:* NOT enrolled in another study ⇒ CONTINUE.
* Enrolled in another study ⇒ STOP. Consult the PSRT regarding safety considerations.
 |  |  |
|  | Review elements infant informed consent as needed. Explain procedures to be performed at today’s visit for the infant. |  |  |
|  | Review/update locator information using site-specific form for the mother and infant. |  |  |
|  | Provide available test results from previous visit for infant.Treat and/or refer for care as required. |  |  |
|  | Complete the **Follow-up Visit Y/N CRF**  |  |  |
|  | Collect/review delivery/baby-well care records and review infant health, anthropometry, feeding history, and medications. * Complete **Infant Feeding Assessment CRF**
* Document any infant medical conditions and/or medications on the **Adverse Event Y/N and Log CRFs** and **Concomitant Medications Log CRF (**infant folder), as needed.
 |  |  |
|  | Administer the appropriate **Ages and Stages Questionnaire** and complete **Infant Ages and Stages Assessment CRF** |  |  |
|  | ***If indicated,*** collect the following amounts of blood and send to lab for testing:* Blood creatinine
	+ [1] mL [color] top [additive/no additive] tube
* 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

*Note: Label all required tubes with a SCHARP-provided PTID label at the time of collection.*  |  |  |
|  | ***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* |  |  |
|  | Perform and document targeted physical exam. Complete **Infant Vital Signs CRF** and **Physical Examination CRF** *(infant folder)* Plot infant weight, length and head circumference on appropriate growth chart. |  |  |
|  | Evaluate findings identified during physical examinations and medical history review. Document in chart notes and update **Concomitant Medications Log, AE Y/N and Log**, if applicable, and document ongoing conditions on **AE Log***.* |  |  |
|  | Provide and explain all available findings and results of infant to mother. Refer for other findings as indicated.  |  |  |
|  | **At the 12-month PPO visit (or if the infant is terminating early)**: Complete **Study Termination CRF** |  |  |
|  | **At the 12-month PPO visit (or if the infant is terminating early):** Complete **Infant 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 **Infant Follow-up Visit Summary CRF** |  |  |
|  | Perform QC1: while participant is still present, review the following for completion and clear documentation:* **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\** Provide contact information and instructions to report symptoms and/or request information and counseling before next visit.
* Offer condoms to mother if not already done.

*\*If indicated after 12-month PPO Visit.* |  |  |
|  | Provide reimbursement. |  |  |
|  | Perform QC2 review and ensure that data is entered in Medidata for the following CRFs/forms:Required CRFs* Follow-up Visit Y/N
* Follow-up Visit Summary- Infant
* Vital Signs- Infant
* Physical Exam
* Infant Feeding Assessment

*As needed* * Chemistry Panel\*
* 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* |  |  |