**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.   * 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 (6 or 12 month)** and complete **Infant Ages and Stages Assessment CRF** |  |  |
|  | Collect the following amounts of blood and send to lab for testing:   * Blood creatinine (*required if born to mother in Truvada group; if indicated for ring group)* * N/A *born to mother in ring group*   + [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   *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. (Refer to MTN-042 HIV Confirmation and Seroconversion Procedure Guide for complete instructions.)   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)* |  |  |
|  | 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):** Review/update the **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 * Chemistry Panel\* *(for Truvada group; if indicated for ring group)*   *As needed*   * HIV Confirmatory Results * Adverse Events Log * Concomitant Medications Log * Hematology Results \*   *\*CRFs/Tools to be completed when lab results are available* |  |  |