**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.

**Mothers who seroconvert should continue with their regularly scheduled visits until the 6-week PPO visit.**

* For visits **before** the 6-week PPO, complete the applicable visit checklist with the modifications as outlined in the “MTN-042 HIV Confirmation and Seroconversion Procedures Guide”.
* **After** the 6-week PPO, participants should continue to be followed on a quarterly schedule and the procedures outlined in this “QUARTERLY SEROCONVERTER CHECKLIST” should be followed.

| **QUARTERLY SEROCONVERTER CHECKLIST** | | | |
| --- | --- | --- | --- |
| **Procedure** | | **Staff Initials** | **Comments:** |
|  | Confirm identity and PTID |  |  |
|  | Check for co-enrollment in other studies per site SOPs:   * NOT enrolled in another study ⇒ CONTINUE. * Enrolled in another study ⇒ Notify PSRT, continue with visit procedures |  |  |
|  | Review elements of informed consent as needed. Explain procedures to be performed at today’s visit. |  |  |
|  | Review/update locator information using site-specific form. |  |  |
|  | Provide available test results from previous visit. Treat and/or refer for care as required. |  |  |
|  | Complete the **Follow-up Visit Y/N CRF.** |  |  |
|  | ***If indicated,*** collect urine (15-60 mL) and perform tests:   * Pregnancy (offer test) * Dipstick urinalysis * Culture per site SOP |  |  |
|  | If social harm has been reported, review/update **Social Impact Log CRF** and document in chart notes. Provide referrals as needed. |  |  |
|  | Review/update as applicable: medical and postpartum care records and concomitant medications, including ARVs; collect/review AEs:   * Document findings, including any AEs on **Adverse Event Y/N and Log CRFs,** and **Concomitant Medications Log CRF,** as needed. |  |  |
|  | Administer and document HIV/STI risk reduction counseling, modified to address primary and secondary prevention, using the **HIV Pre/Post Test and HIV/STI Risk Reduction Counseling Worksheet.**   * Offer condoms |  |  |
|  | Collect the following amounts of blood and send to lab for testing:   * Post HIV Seroconverter Plasma storage   + 15mL purple top (EDTA) tube * CD4+ T cell count   + [X] mL purple top (EDTA) tube * HIV RNA   + [X]mL purple top (EDTA) tube   ***If indicated at all visits*:**   * 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 **Seroconverter Results CRF** and **LDMS Specimen Tracking Sheet.** Complete **Hematology CRF** and/or **Chemistry Panel CRF** as needed. |  |  |
|  | ***If indicated****,* perform and document targeted physical exam. Complete **Vital Signs CRF** and **Physical Examination CRF**. |  |  |
|  | ***If indicated****,* perform and document a pelvic exam per the *Pelvic Exam Checklist*. Document on **Pelvic Exam Diagrams** and **Pelvic Exam CRF.**  ***If indicated****,* collect swabs for   * NAAT for GC/CT/Trich (local lab) * pH assessment (local lab) * Wet prep/KOH mount for candidiasis/BV (can be collected from pH swab)   Document on **STI Test Results CRF.** |  |  |
|  | Evaluate findings identified during any pelvic, physical examinations and/or medical history review. Document in chart notes and update Mother **Concomitant Medications Log, AE Y/N and Log** **CRFs**, if applicable. |  |  |
|  | Provide and explain all available findings and results to participant. Refer for further management/care for HIV, or other findings as indicated.  ***If indicated****,* treat for STI/RTI/UTI per site SOP. |  |  |
|  | **If final quarterly seroconversion visit,** complete **Study Termination CRF** |  |  |
|  | **If final quarterly seroconversion visit**, complete **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 **Follow-up Visit Summary CRF.** |  |  |
|  | Perform QC1: while participant is still present, review the following for completion and clear documentation:   * **LDMS Specimen Tracking Sheet**, **Seroconverter Results CRF** * **AE Logs, and Concomitant Medications Logs** to ensure all conditions, medications, AEs are captured consistently and updated. * **Chart notes** |  |  |
|  | *If indicated,* schedule next quarterly visit.   * Provide contact information and instructions to report symptoms and/or request information, counseling, or condoms before next 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 * Seroconverter Results\*   *As needed*   * Adverse Events Log * Concomitant Medications Log * Vital Signs * Physical Examination * Pelvic Exam * STI Test Results * Hematology * Chemistry Panel * Social Impacts Log   Paper Forms:   * LDMS Specimen Tracking Sheet * HIV Pre-/Post-Test and HIV/STI Risk Counseling Worksheet   *If indicated/applicable*   * Pelvic Exam Diagrams   *\*CRFs/Tools to be completed when lab results are available* |  |  |