**Instructions:** Initiate use of this checklist at the study visit following confirmation of seroconversion. When an item is performed, complete “Staff Initials” cell. If not done but required, write “ND” and staff initials in “Staff Initials” cell, and provide more details in the chart notes as needed. Do not initial for other staff members. If other staff members are not available to initial items themselves, write and initial/ date a note documenting who completed the procedure, e.g., “done by {name}” or “done by nurse.” If visit procedures are split across more than one date, ensure the date is captured in the comments cell for procedures conducted on a date different than that provided above.

| **Seroconverter Visit Procedure** | | **Required at Visits:** | **Staff Initials** | **Comments:** |
| --- | --- | --- | --- | --- |
| 1 | Confirm identity and PTID, check visit window. | All |  |  |
| 2 | Check for co-enrollment in other studies:   * NOT enrolled in another study ==> CONTINUE * Enrolled in a study other than MTN-015 ==> CONTINUE and notify PSRT | All |  |  |
| 3 | Review elements of informed consent as needed | All |  |  |
| 4 | Review/update locator information | All |  |  |
| 5 | Administer Behavior Assessment CRF, if needed based on responses, complete Social Benefit and/or Social Impact Log CRF(s), if log entries have not already been completed within the past three months. | Quarterly, PUEV, Early Term |  |  |
| 6 | Complete Vaginal Practices Y/N and Vaginal Practices, if indicated and the Social Influences Assessment Y/N and the Social Influences Assessment, if indicated. | PUEV, Early Term |  |  |
| 7 | Provide and document:   * HIV Prevention Options Counseling (modified for seroconverters) * STI risk reduction counseling * Provide Condoms * Follow-up on previous referrals (if applicable) * New referrals (if applicable) | All |  |  |
| 8 | Collect urine (15-60 mL) and send to lab for:  Urine hCG (pregnancy) | All |  |  |
| NAAT for GC/CT (first catch urine) | PUEV, Early Term |  |  |
| If indicated, Urine Culture (per local standard of care) | If ind. |  |  |
| 9 | Collect follow-up medical/menstrual/medications history: review/update Adverse Event Log(s) (Adverse Experience Log CRF and Grade 1 Adverse Experience Log), Concomitant Medications Log, and Baseline Medical History Log CRFs. | All |  |  |
| 10 | **If NOT enrolled in MTN-015**  Determine amounts required and collect blood:   * X x X mL lavender top (EDTA) tube, for HIV-1 RNA PCR testing * X x X mL lavender top (EDTA) tube, for CD4+ T cell count * X x X mL lavender top (EDTA) tube, for Seroconverter plasma storage | All |  |  |
| 11 | * X x X mL red top (no additive) tube, for Syphilis | PUEV, Early Term, other visits if ind |  |  |
| 12 | Provide contraceptive counseling. | All |  |  |
| 13 | Prescribe contraceptives (if indicated); document and update Concomitant Medication Log and Family Planning Log, if applicable. | All |  |  |
| 14 | Review pregnancy test results:   * NOT pregnant ==> CONTINUE. * Pregnant, pregnancy newly identified at today’s visit:   + Initiate Pregnancy Management Worksheet *[site to delete if not using]*   + Complete Pregnancy Report and History CRF   + Contact PSRT and refer to PMTCT/HAART per site SOPs * Pregnant, pregnancy first identified at a previous visit:   + If applicable, refer to MTN-016; document in chart notes.   + Follow-up PMTCT referrals per site SOPs | All |  |  |
| 15 | Perform and document targeted physical exam. Complete Vital Signs and Physical Exam CRF. | PUEV, Early Term, if indicated at other visits |  |  |
| 16 | Perform and document pelvic exam per Pelvic Exam Checklist. | PUEV, Early Term, if indicated at other visits |  |  |
| 17 | If STI/RTI/UTI is diagnosed, provide treatment. | If ind. |  |  |
| 18 | Provide and explain all available findings and results. Refer for findings as indicated. | All |  |  |
| 19 | Document any Adverse Events on appropriate Adverse Experience Log or Grade 1 Adverse Experience Log CRF(s) as needed | All |  |  |
| 20 | Schedule next visit. Provide contact information and instructions to report symptoms and/or request information, counseling, or condoms before next visit. | Month 1 & 2, Quarterly |  |  |
| 21 | Complete documentation of how best to contact for study results. As indicated to follow-up on ongoing AEs, schedule next visit. | PUEV, Early Term |  |  |
| 22 | Provide reimbursement. | All |  |  |
| 23 | Perform QC1 while participant is still present to ensure information is complete and accurate.  **All Visits:** Follow-up LDMS Specimen Tracking Sheet  **Additionally at Quarterly Visits:**  Behavior Assessment  **Additionally as Indicated:** Physical, Vital Signs, and Pelvic Exam CRF, Pelvic Exam Diagrams (non-Rave)  **Additionally at PUEV**: Follow-up Visit Summary (assessment of PEP and PrEP use), Ring Adherence, Behavior Assessment, Vaginal Practices, Pelvic Exam, Pelvic Exam Diagrams, AE/GAE/CRFs (and supporting chart notes) as needed, Social Influences Assessment | All, per cell to the left |  |  |
| 24 | Review and submit all required forms into Medidata Rave.  **Month 1&2 Visits:**  Date of Visit, Follow-up Visit Summary, Pregnancy Test Result, Ring Adherence Y/N, Ring Collection and Insertion. Physical, Pelvic Exams, Vital Signs, Ring Adherence, if indicated  **Additionally as Indicated:** Physical Exam, Vital Signs, and Pelvic Exam CRF  **Additionally at Quarterly:** Behavior Assessment Y/N, Baseline Assessment, if applicable.  **Additionally at PUEV:**  Termination, Vaginal Practices, Social Influences Assessment, ACASI Y/N  *Note: seroconverters will not have a scheduled Study Exit Visit. Seroconverters will terminate from the study at their PUEV.*  **Additionally, at all visits per item #13 of this checklist:** Seroconverter Laboratory Results Y/N  Seroconverter Laboratory Results, if indicated  **Log CRFs (if newly-completed or updated):**  Adverse Experience Log, Concomitant Medications Log, Product Hold/Discontinuation Log, Social Harms Log, Social Benefits Log, Protocol Deviations Log, Family Planning Log, Vaginal Ring Tracking Log (if applicable)  **If participant had a newly-positive pregnancy test result or outcome:**  Pregnancy Report and History, Pregnancy Outcome | All, per cell to the left |  |  |