**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 ==> Consult PSRT | All |  |  |
| 3 | Review elements of informed consent as needed | All |  |  |
| 4 | Review/update locator information | All |  |  |
| 5 | Administer Behavior Assessment CRF (If indicated, complete Social Impact Log) | Quarterly,  Semi-ann, PUEV, Early Term |  |  |
| 6 | Administer Social Influences Assessment (SOC-1) | PUEV |  |  |
| 7 | Administer Vaginal Practices CRF | Semi-ann, PUEV, Early Term |  |  |
| 8 | Administer Ring Worries CRF *[If LoA#2 approved, administer at visit following HIV confirmation, otherwise conduct at next quarterly visit]* | Visit following HIV confirmation |  |  |
| 9 | Administer PUEV/Discontinuers ACASI *[If LoA#2 approved, administer at visit following HIV confirmation, otherwise conduct at next quarterly visit]* | Visit following HIV confirmation |  |  |
| 10 | Provide and document:   * HIV-related (including secondary prevention) counseling * STI risk reduction counseling * Provide Condoms * Follow-up on previous referrals (if applicable) * New referrals (if applicable) | All |  |  |
| 11 | Collect urine (15-60 mL) and send to lab for:   * Urine hCG (pregnancy) | All |  |  |
| * NAAT for GC/CT (first catch urine) | Semi-ann |  |  |
| 12 | Collect follow-up medical/menstrual/medications history: review/update Adverse Event Log(s) (AE-1 and GAE-1), and Concomitant Medications Log | All |  |  |
| 13 | **If NOT enrolled in MTN-015**  *Note: the following collections will be performed at the* ***1st, 3rd, 6th, 12th, 18th, and 24th visits after positive HIV rapid results.*** *The Seroconverter Specimen Collection Schedule tool can be used to identify the Visit Months where the below are required.*  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 | Reference collection schedule tool for appropriate Visit Months |  |  |
| 14 | * X x X mL red top (no additive) tube, for Syphilis | PUEV, Early Term |  |  |
| 15 | Provide contraceptive counseling. Note: At PUEV/early term contraceptive counseling can be provided if indicated per local standard of care. | All |  |  |
| 16 | Prescribe contraceptives (if indicated); complete Family Planning CRF. | All |  |  |
| 17 | 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 |  |  |
| 18 | Perform and document targeted physical exam. Complete Abbreviated Physical Exam CRF. | Quarterly, Semi-ann, PUEV, Early Term |  |  |
| 19 | Perform and document pelvic exam per Pelvic Exam Checklist (semi-annual & PUEV). If indicated at other visits, conduct targeted pelvic exam and document per site SOPs. | Semi-ann, PUEV, Early Term |  |  |
| 20 | If STI/RTI/UTI is diagnosed, provide treatment. | All |  |  |
| 21 | Provide and explain all available findings and results. Refer for findings as indicated. | All |  |  |
| 22 | Document any Adverse Events on appropriate AE-1 or GAE-1 Log CRF(s) as needed | All |  |  |
| 23 | Schedule next visit. Provide contact information and instructions to report symptoms and/or request information, counseling, or condoms before next visit. | Monthly, Quarterly, Semi-Ann |  |  |
| 24 | Complete documentation of how best to contact for study results/unblinding. As indicated to follow-up on ongoing AEs, schedule next visit | PUEV, Early Term |  |  |
| 25 | Provide reimbursement | All |  |  |
| 26 | 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, Follow-up LDMS Specimen Tracking Sheet  **Additionally at Semi-annual and PUEV:** Vaginal Practices, Pelvic Exam Diagrams  **Additionally at PUEV**: Social Influences Assessment (SOC-1) | All |  |  |
| 27 | Review and fax all required DataFax forms to SCHARP DataFax.  **Monthly Visits:**  Visit Summary, Monthly Laboratory Results, Ring Adherence, Family Planning  **Additionally at Quarterly Visits:**  Quarterly Laboratory Results (item 1 and 2 marked “not done/not collected”), Behavior Assessment, Abbreviated Physical Exam, Specimen Storage (mark items as “not required” as applicable)  **Additionally at Semi-Annual Visits:**  Pelvic Exam, Vaginal Practices, STI Test Results  **Additionally at PUEV:**  Termination, End of Study Inventory, Social Influences Assessment  *Note: seroconverters will not have a Termination Visit.*  **Additionally, at visits per item #12 of this checklist:** Seroconverter Laboratory Results  **Log CRFs (if newly-completed or updated):**  Adverse Experience Log, Concomitant Medications Log, Social Impact Log, Protocol Deviations Log  **If participant had a newly-positive pregnancy test result or outcome:**  Pregnancy Report, Pregnancy Outcome | All, per cell to the left |  |  |