**Instructions:** The “Required at visits” column lists at which required follow-up visits the item is required per-protocol. When 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.

| **PUEV, Early Termination, and Termination 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 another study ==> CONTINUE and notify PSRT | All |  |  |
| 3 | Review elements of informed consent as needed | All |  |  |
| 4 | Review/update locator information | All |  |  |
| 5 | Administer Ring Adherence CRF | PUEV,  Early Term |  |  |
| 6 | Administer Behavior Assessment CRF (If indicated, complete Social Impact Log) | PUEV,  Early Term |  |  |
| 7 | Administer Social Influences Assessment (SOC-1) | PUEV |  |  |
| 8 | Administer Study Exit Assessment (SEV-1) CRF | Term. |  |  |
| 9 | Administer PUEV/Discontinuers ACASI. | PUEV,  Early Term |  |  |
| 10 | Administer Prevention Studies Experiences CRF, *only if during a Month 3 or 12 Early Termination visit*. | Early Term (M3, M12) |  |  |
| 11 | Administer Vaginal Practices CRF and Ring Worries CRF | PUEV,  Early Term |  |  |
| 12 | Provide and document:   * HIV pre-test counseling * HIV/STI risk reduction counseling * Condoms | All |  |  |
| 13 | Perform and document two Finger Stick HIV tests *[Note to sites: if your site is not doing finger sticks, edit checklist as needed.]* | All |  |  |
| 14 | Provide HIV test results in the context of post-test counseling. Provide referrals if needed/requested.   * If both tests negative ==> UNINFECTED ==> CONTINUE. * If at least one test positive ==> Collect blood sample for WB, viral load, and CD4 testing and for HIV confirmation storage. If applicable, arrange to collect product not returned today within 24 hours. | All |  |  |
| 15 | Collect urine (15-60 mL) and send to lab for:   * Urine hCG (pregnancy) | All |  |  |
| * NAAT for GC/CT (first catch urine) | If ind. |  |  |
| 16 | Collect vaginal fluid for archive (self-collection) | All |  |  |
| 17 | Collect follow-up medical and menstrual history with documentation of current medications and complete/update AE Log, GAE Log, Family Planning CRF, and Concomitant Medications Log CRFs as needed. | All |  |  |
| 18 | Determine amounts required and collect blood:   * X x X mL lavender top (EDTA) tube, for CBC with platelets * X x X mL red top (no additive) tube, for Serum Chemistries * X x X mL red top (no additive) tube, for Syphilis | PUEV,  Early Term |  |  |
| 19 | Determine amounts required and collect blood:   * X x X mL lavender top (EDTA) tube, for routine plasma storage | All |  |  |
| 20 | Review pregnancy test results:   * NOT pregnant ==> CONTINUE. * Pregnant, pregnancy newly identified at today’s visit:   + If applicable, arrange to collect product not returned today within 5 working days.   + Initiate Pregnancy Management Worksheet *[site to delete if not using]*   + Complete Pregnancy Report and History CRF * Pregnant, pregnancy first identified at a previous visit:   + If applicable, refer to MTN-016; document in chart notes. | All |  |  |
| 21 | Perform and document abbreviated physical exam | PUEV,  Early Term |  |  |
| 22 | Perform and document pelvic exam per Pelvic Exam Checklist | PUEV,  Early Term |  |  |
| 23 | If STI/RTI/UTI is diagnosed, provide treatment. | All |  |  |
| 24 | Provide contraceptive counseling and prescribe contraceptives if indicated (per local standard of care); document and update Concomitant Medication log if applicable. | If ind |  |  |
| 25 | Provide and explain all available findings and results. Refer for findings as indicated. | All |  |  |
| 26 | Document any Adverse Events. If required based on all available information, complete/update Grade 1 AE Log CRF and/or AE Log CRF(s) | All |  |  |
| 27 | At **scheduled** PUEV, complete Vaginal Ring Request Slip by marking “product use period completed” and send to pharmacy.  If early termination and participant has not already been discontinued from product, mark the Vaginal Ring Request Slip “permanent discontinuation” and send to pharmacy. | PUEV,  Early Term |  |  |
| 28 | Have participant (or clinician/designee) remove used vaginal ring. (NOTE: if pelvic conducted, remove ring prior to exam). Collect and document on RingCollection/Insertion CRF. Collect ring for lab storage. If applicable, collect/document return of any unused rings on Ring Collection/Insertion CRF and send to pharmacy for quarantine. | All |  |  |
| 29 | Collect used ring for lab storage. | All |  |  |
| 30 | Document ring collection on the Study Product Accountability Log | PUEV,  Early Term |  |  |
| 31 | Schedule study exit/termination visit. Provide contact information and instructions to report symptoms and/or request information, counseling, or condoms before next visit. | PUEV |  |  |
| 32 | Complete documentation of how best to contact for study results/unblinding. As indicated per protocol, arrange future contact for follow-up on ongoing AEs. | Early Term,  Term. |  |  |
| 33 | Provide reimbursement | All |  |  |
| 34 | Perform QC1 to ensure chart notes and all other required visit documentation is complete.  **At PUEV or early termination visit:**  Visit Summary (items 2 and 3), Prevention Study Experiences (*Month 3 or 12 only*), Ring Adherence, Behavior Assessment, Vaginal Practices, Ring Worries, Family Planning, Pelvic Exam Diagrams, Follow-up LDMS Specimen Tracking Sheet, AE/GAE CRFs (and supporting chart notes) as needed  **Additionally at PUEV:**  Social Influences Assessment CRF  **At Study Exit/Termination visit:**  Visit Summary (items 2 and 3), Review AE Log, GAE Log, Product Hold/Discontinuation Log, Study Exit Assessment, and Concomitant Medications Log to ensure all pages/entries are closed out. | All |  |  |
| 35 | Review and fax all required DataFax forms to SCHARP DataFax.  **PUEV:**  Visit Summary, Monthly Laboratory Results, Specimen Storage, Ring Adherence, Family Planning, Ring Collection/Insertion, Quarterly Laboratory Results, Behavior Assessment, Abbreviated Physical Exam, Pelvic Exam, Vaginal Practices, STI Test Results, PUEV Laboratory Results, Ring Worries, Follow-up ACASI Tracking, Social Influences Assessment  **Additionally at Early Termination Visit:**  Prevention Study Experiences (*Month 3 or 12 only*), Termination, End of Study Inventory  **Study Exit/Termination Visit:**  Visit Summary, Specimen Storage, Monthly Laboratory Results, Study Exit Assessment, Termination, End of Study Inventory  **Log CRFs (if newly-completed or updated):**  Adverse Experience Log, Concomitant Medications Log, Product Hold/Discontinuation Log (updates only), Social Impact Log, Protocol Deviation Log. | All as specified to the left |  |  |