**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. | 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 | Complete Behavior Assessment Y/N CRF and administer Behavior Assessment CRF. If needed based on responses, complete Social Benefit and/or Social Impact CRF. | PUEV, Early Term |  |  |
| 6 | Complete Ring Adherence Y/N CRF and administer Ring Adherence CRF, if indicated. | PUEV,  Early Term |  |  |
| 7 | If the participant has not previously discontinued study product, administer PUEV/Discontinuers ACASI. Complete ACASI Y/N and ACASI Tracking CRFs. | PUEV,  Early Term |  |  |
| 8 | Complete Vaginal Practices Y/N CRF and administer Vaginal Practices CRF. | PUEV,  Early Term |  |  |
| 9 | Complete Social Influences Y/N CRF and administer Social Influences CRF and Social Influences Supplement (if available) | PUEV,  Early Term |  |  |
| 10 | Complete Study Exit Assessment Y/N CRF and administer the Study Exit Assessment CRF. | Term |  |  |
| 11 | Provide and document HIV pre-test counseling. | All |  |  |
| 12 | Perform and document two Finger Stick HIV tests *[Note to sites: if your site is not doing finger sticks, edit checklist as needed.]* | All |  |  |
| 13 | Collect urine (15-60 mL) and send to lab for:   * Urine hCG (pregnancy) | All |  |  |
| * NAAT for GC/CT | PUEV, Early Term;  If indicated at Term |  |  |
| * If indicated, urine culture per local standard of care | If ind. |  |  |
| 14 | Collect vaginal fluid for archive (self-collection) | All |  |  |
| 15 | Collect hair sample for PK for DPV testing and archive | All |  |  |
| 16 | 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 plasma storage, Confirmatory Test (Geenius), HIV viral load, and CD4+ testing.   + If applicable, collect ring for laboratory storage and testing. If ring not returned, arrange to collect ring within 24 hours as applicable.   + AT **PUEV:**     - **If confirmed HIV positive with Geenius testing:** do not schedule SEV, proceed with termination of participant procedures that day.     - **If Geenius is negative or indeterminate:** continue required algorithm testing and LC notification, schedule SEV visit, do not complete termination procedures   + AT **SEV:**      - **If confirmed HIV positive with Geenius testing:** proceed with termination procedures that day.     - **If Geenius is negative or indeterminate:** continue required algorithm testing and contact LC, wait to terminate participant until HIV status is finalized. | All |  |  |
| 17 | Provide and document HIV prevention options counseling using the “End Visit, Month 12” section of the flipchart, including offering condoms. | PUEV, Early Term |  |  |
| 18 | Provide and document HIV/STI risk reduction counseling, including offering condoms. | Term. |  |  |
| 19 | Determine amounts required and collect blood:   * X x X mL lavender top (EDTA) tube, plasma sample for DPV testing and archive | All |  |  |
| * 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 |  |  |
| 20 | Collect follow-up medical/menstrual/medications history: review/update Adverse Experience Log, Grade 1 Adverse Experience Log, Concomitant Medications Log, Baseline Medical History Log CRFs. | All |  |  |
| 21 | Perform physical exam and document on the Vital Signs and Physical Exam CRF | PUEV,  Early Term, If indicated at Term |  |  |
| 22 | For participants who ever accepted the ring:   * Complete study product request slip by marking “Participant No Longer in the study” and send to pharmacy. * If indicated, have participant (or clinician/designee) remove used vaginal ring, collect used ring(s), send to lab for storage, and document on Ring Collection/Insertion CRF, Vaginal Ring Tracking Log, and accountability log. If applicable, collect/document return of unused rings on Ring Collection/Insertion CRF and send to pharmacy for quarantine.   *Note: Completion of the Ring Collection and Insertion CRF is required, regardless of whether the participant is returning rings or not* | PUEV,  Early Term |  |  |
| 23 | Perform and document pelvic exam per Pelvic Exam Checklist (NOTE: if participant is using the ring, remove ring prior to exam). | PUEV,  Early Term  If indicated at Term |  |  |
| 24= | Provide contraceptive counseling, offer contraceptives if indicated | PUEV, Early Term; if Ind at Term |  |  |
| 25 | 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   + If applicable, refer to MTN-016; document in chart notes. * Pregnant, pregnancy first identified at a previous visit:   + If applicable, refer to MTN-016; document in chart notes. | All |  |  |
| 26 | If STI/RTI/UTI is diagnosed, provide treatment. | If ind |  |  |
| 27 | Provide and explain all available findings and results. Refer for findings as indicated. | All |  |  |
| 28 | 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 |  |  |
| 29 | Schedule study exit/termination visit using SEV calculator (print and file). Provide contact information and instructions to report symptoms and/or request information, counseling, or condoms before next visit. | PUEV |  |  |
| 30 | Complete study exit worksheet and permission to contact log. As indicated per protocol, arrange future contact for follow-up on ongoing AEs. | Early Term,  Term. |  |  |
| 31 | Provide reimbursement | All |  |  |
| 32 | Perform QC1 to ensure chart notes and all other required visit documentation is complete.  **At PUEV or early termination visit:**  Follow-up Visit Summary (PreP and PEP), Ring Adherence, Behavior Assessment, Social Influences Assessment, Vaginal Practices, Pelvic Exam Diagrams, Pregnancy Test Result (LMP dates), Follow-up LDMS Specimen Tracking Sheet, AE/GAE log CRFs, Vaginal Ring Tracking Log (participant reported items), Family Planning Log (and supporting chart notes) as needed  **At Study Exit/Termination visit:**  Follow-up Visit Summary (PrEP and PEP), Study Exit Assessment, Pregnancy Test Result (LMP dates), Review AE Log, GAE Log, Product Hold/Discontinuation Log, Concomitant Medications Log, Social Impact Log to ensure all pages/entries are closed out. | All |  |  |
| 33 | Review and submit all required Case Report Forms in Medidata Rave.  **PUEV:**  Date of Visit, Follow-up Visit Summary, Laboratory Results, Specimen Storage, Ring Adherence Y/N, Ring Adherence (if indicated), Ring Collection and Insertion, HIV Test Results, Pregnancy Test Result, Behavior Assessment Y/N and Behavioral Assessment, Physical Exam, Vital Signs, Pelvic Exam, Vaginal Practices Y/N and Vaginal Practices, Social Influences Assessment Y/N and Social Influences Assessment, Social Influences Supplement (if available) STI Test Results, ACASI Tracking Y/N and ACASI Tracking, Concomitant Medications Y/N, Adverse Experience Y/N  **Additionally at Early Termination Visit:**  Termination, Study Exit Assessment CRF (and Y/N Prompt)  **Study Exit/Termination Visit:**  Date of Visit, Follow-up Visit Summary, Specimen Storage, HIV Test Results, Pregnancy Test Result, Termination, Study Exit Assessment (and Y/N prompt), Concomitant Medications Y/N, Adverse Experience Y/N  **Log CRFs (if newly-completed or updated):**  Adverse Experience Log, Concomitant Medications Log, Clinical Product Hold/Discontinuation Log (updates only), Social Impact Log, Social Benefit Log, Vaginal Ring Tracking Log, Protocol Deviation Log, Family Planning Log | All as specified to the left |  |  |