**Instructions:** Complete staff initials next to procedures completed. Do not initial for other staff members. If other staff members are not available to initial checklist items themselves, initial and date a note on the checklist documenting who completed the procedure, e.g., “done by {name}” or “done by nurse.” 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.

| **Procedure** | | **Staff Initials** | **Comments:** |
| --- | --- | --- | --- |
|  | Confirm identity and PTID |  |  |
|  | Review elements of informed consent/assent as needed. Explain procedures to be performed at today’s visit/phone call. |  |  |
|  | Review/update locator information using site-specific form. |  |  |
|  | Provide available test results from previous visit. Treat and/or refer for care as required. |  |  |
|  | Log into the MTN-034 Medidata Rave database, and select the appropriate PTID. Begin visit by opening the applicable Visit folder. Complete the **Follow-up Visit Yes/No** **CRF**. |  |  |
|  | Collect follow-up medical/contraceptive/medications history and document any adverse events; review/update:   * **Adverse Event Log CRF** * **Concomitant Medications Log CRF** * **Family Planning Log CRF** * **Social Impacts/ Benefits Log CRF** |  |  |
|  | ***If indicated*,** provide contraceptive counseling and document on **Contraceptive Counseling Worksheet** |  |  |
|  | ***If indicated*,** provide HIV/STI risk reduction counseling and document on the **HIV Pre-/Post-Test and HIV/STI Risk Counseling Worksheet** |  |  |
|  | **For Visits 3, 10, and 17 ONLY**, if not vaccinated against HPV and/or HBV, offer. If accepted, provide at next study visit or separate clinic visit, if applicable, or refer for HBV and/or HPV vaccine series. Document on the **Concomitant Medications Log CRF.**  *NOTE: For enrolled participants who decline vaccination, the vaccine series may be initiated at any time during follow-up.* |  |  |
|  | Provide and explain all available findings and results to participant. Refer for other findings as indicated.  ***If indicated****,* treat for STI/RTI/UTI per local standard of care. |  |  |
|  | **At Visit 24/SEV ONLY (for study exit):**   * Complete **Study Discontinuation CRF** |  |  |
| * 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. |  |  |
|  | **For Visits 3, 10, and 17 ONLY,** provide protocol adherence counseling by instructing participant of the following:   * For 72 hrs (3 days) prior to study visits:   + Abstain from non-study vaginal products and/or practices including but are not limited to spermicides, diaphragms, vaginally applied medication, menstrual cups, cervical caps, douches, lubricants, sex toys, etc.   + Stay sexually abstinent (i.e., no receptive intercourse - vaginal, anal, oral and finger stimulation). * For entire study:   + Refrain from using non-study PrEP.   + If PEP is used, study product will be temporarily held. Note that participants should be offered PEP if they have a known or potential HIV exposure during the study, as soon as possible and within 72 hours of exposure.   Participants should be encouraged to inform study staff if they have not been able to follow the above guidelines. Document any questions or issues on this checklist or in chart notes. |  |  |
|  | **For Visits 3, 10, and 17 ONLY**, ask if the participant has any questions or concerns about the following:   * Study product (ring/tablet) she is currently taking * Study adherence menu options and if she wants to make any changes.   Document participant responses on this checklist or in chart notes. |  |  |
|  | Complete the **Follow-up Visit Summary** **CRF.** |  |  |
|  | Perform QC1: while participant is still present (on the phone or at the clinic), review the following for completion and clear documentation:   * **Follow-Up Visit Summary** **CRF** * **AE Log(s)** and **Concomitant Medications Log CRFs** to ensure all conditions, medications, AEs are captured consistently and updated. * **Chart notes** |  |  |
|  | Schedule next visit\*   * Provide contact information and instructions to report symptoms and/or request information, counseling, a new ring/tablets, or condoms before next visit.   *\*If indicated after Visit 24/SEV.* |  |  |
|  | Provide reimbursement. |  |  |
|  | Perform QC2 review and ensure that data is entered in Medidata for the following CRFs/forms:  Required CRFs   * Follow-up Visit Summary * Study Termination (Visit 24/ SEV ONLY)   *As needed:*   * Family Planning Log * Adverse Events Summary/ Log * Concomitant Medications Summary/ Log * Social Impacts Summary/ Log * Social Benefits Summary/ Log   Paper Forms:   * HIV Pre/Post-Test and Risk Counseling Worksheet, *if indicated* * Contraceptive Counseling Worksheet, *if indicated* * Study Exit Worksheet (Visit 24/SEV ONLY) * Permission to Contact Log (Visit 24/SEV ONLY) |  |  |