**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 on PEP and non-study PrEP

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)
 |  |  |