**Instructions:** The “Required at visits” column indicates when the item is required during follow-up per-protocol. Procedures do not have to be conducted in the order in which they appear in the checklist. 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.

| **Month 1, 2, or Quarterly Follow-Up Procedure** | **Required at visits:** | **Staff Initials** | **Comments:** |
| --- | --- | --- | --- |
| 1. 1
 | Confirm identity and PTID | All |  |  |
| 1. 2
 | Check for co-enrollment in other studies:* NOT enrolled in another study ==> CONTINUE
* Enrolled in another study ==> CONTINUE and notify PSRT
 | All |  |  |
| 1. 3
 | Review elements of informed consent as needed | All  |  |  |
| 1. 4
 | Review/update locator information  | All |  |  |
| 1. 5
 | At Quarterly Visits only: Administer Behavior Assessment CRF. If needed based on responses, complete Social Benefit and/or Social Impact Log CRF(s).  | Quarterly |  |  |
| 1. 6
 | Administer Ring Adherence CRF | All |  |  |
| 1. 7
 | At Month 3 Only: Administer ACASI QuestionnaireComplete ACASI Tracking CRF  | Month 3 |  |  |
| 1. 8
 | Provide and document HIV pre-test counseling | All |  |  |
| 1. 9
 | Perform and document two Finger Stick HIV tests *[Note to sites: if your site is not doing finger sticks, edit checklist as needed.]* | All |  |  |
| 1. 10
 | Provide and document HIV prevention options counseling/protocol counseling, including offering condoms.Does participant choose to accept the ring at this visit? * Yes
* No
 | All |  |  |
| 1. 11
 | 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 **==>**
	+ Complete clinical HOLD documentation regardless of whether participant was previously accepting rings
	+ Complete VR request slip indicating HOLD only for participants who have ever had a prescription completed
	+ 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.
 | All |  |  |
| 1. 12
 | Collect urine (15-60 mL) and send to lab for:* Urine hCG (pregnancy)
 | All |  |  |
| * If indicated, NAAT for GC/CT (first catch urine)
* If indicated, Urine culture (per local standard of care)
 | If ind. |  |  |
| 1. 13
 | Collect vaginal fluid for archive (self-collection) | All |  |  |
| 1. 14
 | Collect hair sample  | All |  |  |
| 1. 15
 | Determine amounts required and collect blood:* *X x X mL lavender top (EDTA) tube, for HIV testing [include on checklist only if not performing Finger Stick HIV rapids]*
 | All |  |  |
| * X x X mL lavender top (EDTA) tube, for plasma storage
 | All |  |  |
| * If indicated, X x X mL red top (no additive) tube, for Serum Chemistries
* If indicated, X x X mL red top (no additive) tube, for Syphilis
 | If ind. |  |  |
| 1. 16
 | 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 |  |  |
| 1. 17
 | If indicated, perform and document targeted physical exam. Complete Vital Signs CRF and Physical Exam CRF. | If ind. |  |  |
| 1. 18
 | If indicated, perform and document pelvic exam per Pelvic Exam Checklist   | If ind. |  |  |
| 1. 19
 | Provide contraceptive counseling | All |  |  |
| 1. 20
 | Review pregnancy test results:* NOT pregnant ==> CONTINUE.
* Pregnant, pregnancy newly identified at today’s visit:
	+ Complete clinical HOLD documentation regardless of whether participant was previously accepting rings
	+ Complete VR request slip indicating HOLD only for participants who have ever had a prescription completed
	+ 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:
	+ Continue to HOLD study product
	+ If applicable, refer to MTN-016; document in chart notes.
 | All |  |  |
| 1. 21
 | Prescribe contraceptives if indicated; document and update Concomitant Medication Log and Family Planning Log if applicable. | All |  |  |
| 1. 22
 | If STI/RTI/UTI is diagnosed, provide treatment. | If ind. |  |  |
| 1. 23
 | Provide and explain all available findings and results. Refer for findings as indicated. | All |  |  |
| 1. 24
 | Document any Adverse Events: Complete Grade 1 Adverse Experience Log CRF and/or Adverse Experience Log CRF(s) as needed | All |  |  |
| 1. 25
 | If participant chooses ring, assess clinical eligibility to receive a ring and complete vaginal ring request slip (or prescription if initiating ring use) as appropriate and send to pharmacy.  | If ind. |  |  |
| 1. 26
 | If applicable, have participant (or clinician/designee) remove used vaginal ring. Collect used ring(s), send to lab for storage, and document on Ring Collection and Insertion CRF, ring accountability log, and Vaginal Ring Tracking Log. As needed, send returned unused rings to pharmacy for quarantine. (NOTE: if pelvic conducted, used ring will have been removed prior to exam).  | If ind. |  |  |
| 1. 27
 | If applicable, provide vaginal ring(s) to participant for self-insertion and document on the Study Product Accountability Log and Vaginal Ring Tracking Log. As needed, review any ring insertion instructions and address participant questions. | If ind. |  |  |
| 1. 28
 | If indicated, confirm placement of the vaginal ring through digital examination | If ind.  |  |  |
| 1. 29
 | Schedule next visit. Provide contact information and instructions to report symptoms and/or request information, counseling, a new ring, or condoms before next visit. Update the Participant Tracking Database (or site-specific tracking documents). | All |  |  |
| 1. 30
 | Provide reimbursement | All  |  |  |
| 1. 31
 | Perform QC1 while participant is still present to ensure information is complete and accurate.**All visits:** Follow-up Visit Summary (items 2-3a), Ring Adherence, Vaginal Ring Tracking Log (if applicable), Family Planning Log, Follow-up LDMS Specimen Tracking Sheet, Adverse Experience Log/Grade 1 Adverse Experience Log CRFs (and supporting chart notes) as needed, Physical, Vital Signs, and Pelvic Exam CRFs as indicated. **Additionally at Quarterly Visits:** Behavior Assessment | All, as required |  |  |
| 1. 32
 | Review and submit all required Case Report Forms in Medidata Rave.**All visits:** Follow-up Visit Summary, HIV Test Results, Ring Adherence, Ring Collection and Insertion, Ring Adherence, Specimen Storage, Physical, Vital Signs, Pregnancy Test Result, Specimen Storage, and Pelvic Exams if indicated**Month 3 Visit:** ACASI Tracking**Additionally at Quarterly Visits:** Behavior Assessment **Log CRFs (if newly-completed or updated):**Adverse Experience Log, Concomitant Medications Log, Baseline Medical History Log, Family Planning Log, Vaginal Ring Tracking Log, Clinical Product Hold/Discontinuation Log, Social Impact Log, Social Benefits Log, Protocol Deviations Log**If participant had a positive rapid HIV test result:**HIV Test Results**If participant had a newly-positive pregnancy test result or outcome:**Pregnancy Report and History, Pregnancy Outcome | All, as required |  |  |