**Instructions:** All procedures listed below are required for interim visits conducted for participants who opt to collect rings monthly during the quarterly follow-up period. These visits may be conducted at the research clinic or off-site. 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.

| **Ring Pick Up Visit Checklist** |
| --- |
|  **Procedure** | **Required at visits:** | **Staff Initials** | **Comments:** |
| 1 | Confirm identity and PTID per site SOPs.  | 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 | Conduct verbal check for AEs. AE reported?* Yes – review/update Adverse Experience Log
* No
 | All |  |  |
| 5 | Does the participant have a negative HIV test documented within the previous 90 days? * Yes – proceed to item #9
* No – continue to item #6
 | All |  |  |
| 6 | Provide and document HIV pre-test counseling | If Ind. |  |  |
| 7 | Perform and document two Finger Stick HIV tests *[Note to sites: if your site is not doing finger sticks, edit checklist as needed.]* | If Ind. |  |  |
| 8 | 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.  | If Ind. |  |  |
| 9 | Does the participant have a negative pregnancy test documented within the previous 90 days? * Yes – proceed to item #12
* No – continue to item #10
 | All |  |  |
| 10 | Collect urine (15-60 mL) and send to lab for:* Urine hCG (pregnancy)
 | If Ind. |  |  |
| 11 | 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.
 | If Ind. |  |  |
| 12 | Complete vaginal ring request slip (or prescription) as appropriate and send to pharmacy. Liaise with pharmacy if needed for completion of Pharmacy Ring Dispensation CRF.  | All |  |  |
| 13 | 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. | All |  |  |
| 14 | 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. | All |  |  |
| 15 | Confirm scheduling of next visit. Provide contact information and instructions to report symptoms and/or request information, counseling, a new ring, or condoms before next visit. | All |  |  |
| 16 | Provide reimbursement as needed/indicated | All |  |  |
| 17 | QC to ensure chart notes and all other required visit documentation is complete. | All |  |  |
| 18 | If applicable, enter any completed CRFs into Medidata. At a minimum, the Date of Visit, Interim Visit Procedures, Follow-up Visit Summary, Ring Collection and Insertion, and Vaginal Ring Tracking Log forms are required | All |  |  |