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| **Week 4 (Visit 4.0) and Week 8 (Visit 5.0) Follow-Up Visit Checklist** |

|  **Procedure** | **Staff Initials** | **Comments:** |
| --- | --- | --- |
| 1 | Confirm identity and PTID. |  |  |
| 2 | Check for co-enrollment in other studies:* NOT enrolled in another study ==> CONTINUE.
* Enrolled in another study ==> STOP. NOT ELIGIBLE.
 |  |  |
| 3 | Review elements of informed consent as needed. Explain procedures to be performed at today’s visit. |  |  |
| 4 | Review/update locator information using site-specific form. |  |  |
| 5 | Provide available test results from previous visit. Treat and/or refer for care as required. |  |  |
| 6 | Administer Ring Adherence CRF. |  |  |
| 7 | Administer Vaginal Practices CRF. |  |  |
| 8 | Administer Follow-up CASI Questionnaire.  |  |  |
| 9 | Provide and document the following on the appropriate counseling worksheet or [site-specific source document]. Provide male condoms if needed.* Protocol adherence counseling
* HIV/STI risk reduction counseling

If indicated:* HIV pre and post-test counseling
* Male condom counseling
 |  |  |
| 10 | Collect follow-up medical/ medications history: review/update Follow-up Medical History Log, AE Log CRF, and Concomitant Medications Log CRFs. |  |  |
| 11 | If indicated, collect (15-60mL) urine for: * NAAT for GC/CT
* Dipstick urinalysis and/or urine culture
 |  |  |
| 12 | Collect blood for:* PK [10 mL]

If clinically indicated: Testing is based on local lab requirements; tailor this item to reflect site-specific tube type and volume.* HIV serology
* CBC with platelets
* Serum Chemistries

If indicated, review HIV test results:* HIV negative ==> CONTINUE.
* HIV positive ==> STOP. NOT ELIGIBLE.

Document results on Pharmacokinetics, Safety Laboratory Results and HIV Results CRFs as needed. |  |  |
| 13 | Perform targeted physical exam. Complete Physical Exam CRF. |  |  |
| 14 | Perform and document pelvic exam per Pelvic Exam Checklist.  |  |  |
| 15 | If STI/RTI/UTI is diagnosed, provide treatment. |  |  |
| 16 | Provide and explain all available findings and results. Refer for findings as indicated. |  |  |
| 17 | Assess/document any adverse events. Complete/update AE Log CRF(s) as needed. |  |  |
| 18 | Assess eligibility and participant’s willingness to continue product use. Complete the MTN-024/IPM 031 Vaginal Ring Request Slip and deliver white original to the pharmacist, per site SOPs.  |  |  |
| 19 | Provide new vaginal ring to participant for self-insertion and ask her to insert the ring. As needed, review any ring insertion and removal instructions and address participant questions. |  |  |
| 20 | Confirm placement of the vaginal ring through digital (bimanual) examination. |  |  |
| 21 | Document the provision of the vaginal ring to the participant using the Clinic Study Product Accountability Log and Ring Collection and Insertion CRF. |  |  |
| 22 | Provide ring use adherence counseling *[document on Ring Use Adherence Key Messages Worksheet or site specific document]* |  |  |
| 23 | 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 site-specific tracking documents. |  |  |
| 24 | If needed, provide study approved lubricant and Study-Approved Lubricant Use Log with instructions to complete if she chooses to use study-provided lubricant provided within the 72 hours prior to her next clinic visit. |  |  |
| 25 | Perform QC1 while participant is still present to ensure information is complete and accurate.**All visits:** Follow-up visit summary, Physical Exam, Pelvic Exam and Pelvic Exam Diagrams (non-DataFax), Pharmacokinetics, Follow-up CASI Tracking, Ring Collection and Insertion, Ring Adherence, Specimen Storage Vaginal Practices. |  |  |
| 26 | Provide reimbursement. |  |  |
| 27 | Perform QC2 and DataFax forms to SCHARP DataFax.**All visits:** Follow-up Visit Summary, Physical Exam, Follow-up CASI Tracking, Pelvic Exam and Pelvic Exam Diagrams (non-DataFax), Pharmacokinetics, Ring Collection and Insertion, Ring Adherence, Specimen Storage and Vaginal Practices.**Log CRFs (if newly-completed or updated):**Adverse Experience Log, Concomitant Medications Log, Product Hold/Discontinuation Log, Protocol Deviations Log |  |  |