**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 the “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.”

| **GROUP 2 FEMALE Follow-up Procedures**  | **Required at visits:** | **Staff Initials** |
| --- | --- | --- |
| Visits 3a, 4, 5, 6, 7a, 8 |
| 1 | Confirm identity and PTID | All |  |
| 2 | Check for co-enrollment in other studies:* NOT enrolled in another study ==> CONTINUE
* Enrolled in another study ==> Consult PSRT
 | All |  |
| 3 | Review elements of informed consent as needed | All  |  |
| 4 | Review/update locator information  | All |  |
| 5 | Confirm continued participant monogamy* Monogamous ==> CONTINUE
* Not monogamous ==> STOP. Terminate participant and partner from study
 | All |  |
| 6 | Collect used applicators; collect unused study product if any.Update Study Product Accountability CRF from previous visit. | Visits 3a, 5, 7a |  |
| 7 | Collect follow-up medical/menstrual/medications history: review/update AE Log, and Concomitant Medications Log CRFs.  | All |  |
| 8 | Provide contraceptive counseling | All |  |
| 9 | Provide modified HIV/STI risk reduction counseling | Visits 3a, 4, 6, 7a, 8 |  |
| 10 | Collect urine (15-60 mL) and send to lab for urine hCG (pregnancy). If indicated, NAAT for GC/CT and urine culture | All |  |
| 11 | Collect vaginal fluid for pH assessment  | Visits 3a, 4, 6, 7a, 8 |  |
| 12 | Perform and document modified physical exam. Complete Physical Exam CRF for female participants. | Visits 3a and 7a |  |
| 13 | If indicated, perform and document pelvic exam per Pelvic Exam Checklist. Complete a new Pelvic Exam Diagrams and Clinically-indicated Pelvic Exam CRF.  | Visits 3a, 4, 6, 7a, 8 |  |
| 14 | If STI/RTI/UTI is diagnosed, provide treatment. | All |  |
| 15 | Provide and explain all available findings and results. Refer for findings as indicated. | All |  |
| 16 | Document and report Adverse Events per site SOP | Visits 3a and 7a |  |
| 17 | Provide logistical information and instructions for coitus. Offer panty liners  | Visits 3a and 7a |  |
| 18 | Provide one applicator of study product and study product use instructions | Visit 3a  |  |
| 19 | Provide protocol adherence counseling | Visit 7a |  |
| 20 | Provide study product, study product use instructions and product adherence counseling; offer panty liners. Participant to insert first dose for each visit in clinic.* 7 applicators for Visit 4
* 8 applicators for Visits 6 and 8

Complete Study Product Accountability CRF for this visit. | Visits 4, 6, 8 |  |
| 21 | Provide contact information and instructions to report symptoms and/or request information before next visit | Visits 4, 6, 8 |  |
| 22 | Schedule next visit, if applicable | Visits 3a and 7a |  |
| 23 | Provide reimbursement | Visits 3a and 7a |  |
| 24 | Review and fax all required DataFax forms to SCHARP DataFax. | Visits 4, 6, 8 |  |
| Visits 3b, 5, 7b |
| 25 | Collect used applicator; collect unused applicator if any.Update Study Product Accountability CRF from previous visit. | Visits 3b, 5, 7b |  |
| 26 | Collect post coitus timing information from participant and record on the Visit Summary CRF. | Visits 3b and 7b |  |
| 27 | Conduct CASI Behavioral Questionnaire | Visits 3b, 5, 7b |  |
| 28 | Approximately 2 hours after coitus, perform pelvic exam per pelvic exam checklist. Complete a new Pelvic Exam Diagrams and Pelvic Exam CRF. hr min\_\_\_\_\_\_\_: \_\_\_\_\_\_\_ following coitusNote: Sampling for Visit 5 should occur at similar time point to Visit 3b. Sampling for Visit 9 should occur at similar time point to Visit 7b. | Visits 3b, 5, 7b |  |
| 29 | Collect 10 mL blood for PK | Visits 3b, 5, 7b |  |
| 30 | Document and report Adverse Events per site SOP | Visits 3b, 5, 7b |  |
| 31 | Provide contact information and instructions to report symptoms and/or request information before next visit | Visits 3b, 5, 7b |  |
| 32 | Schedule next visit, if indicated  | Visits 3b, 5, 7b |  |
| 33 | Provide reimbursement | Visits 3b, 5, 7b |  |
| 34 | Review and fax all required DataFax forms to SCHARP DataFax.**Visits 3a/3b, 4, 5, 6, 7/7b, 8:*** Visit Summary (Visits 3a/3b, 4, 5, 6, 7a/7b, 8)
* Physical Exam (Visits 3a, 7a)
* Pelvic Exam (Visits 3b, 5, 7b)
* Clinically-indicated Pelvic Exam (Visits 3a, 4, 6, 7a, 8 if indicated)
* STI Test Results (Visits 3a/3b (single form), 4, 5, 6, 7a/7b (single form), 8)
* Pharmacokinetics (Visits 3b, 5, 7b)
* Study Product Accountability (Visits 3a, 4, 5, 6, 8)
* Group 2 – Participant-reported Dosing (Visits 5, 7a)
* Pelvic Exam Diagrams (non-DataFax) (Visits 3b, 5, 7b) (Visits 3a, 4, 6, 7a, 8 if indicated)
* LDMS Specimen Tracking Sheet (non-DataFax) (Visits 3b, 5, 7b)
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