**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.” Note: Visits 5b and 6b will occur approximately 1 day after Visits 5a and 6a respectively, so checklist items for Visits 5b and 6b must include initials and date.

| **GROUP 1 FEMALE Follow-up Procedures**  | **Required at visits:** | **Staff Initials** |
| --- | --- | --- |
| Visits 3a, 4a, 5a, 6a, 7a |
| 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
 | Visits 3a, 4a, 5a, 6a |  |
| 6 | Collect follow-up medical/menstrual/medications history: review/update AE Log, and Concomitant Medications Log CRFs.  | All |  |
| 7 | Provide contraceptive counseling | All |  |
| 8 | Provide modified HIV/STI risk reduction counseling | All |  |
| 9 | Collect urine (15-60 mL) and send to lab for urine hCG (pregnancy). If indicated, NAAT for GC/CT and urine culture | All |  |
| 10 | Collect vaginal fluid for pH assessment  | All |  |
| 11 | Perform and document modified physical exam. Complete Physical Exam CRF for female participants. | All |  |
| 12 | If indicated, perform and document pelvic exam per Pelvic Exam Checklist. Complete a new Pelvic Exam Diagrams and Clinically-indicated Pelvic Exam CRF.  | All |  |
| 13 | If STI/RTI/UTI is diagnosed, provide treatment. | All |  |
| 14 | Provide and explain all available findings and results. Refer for findings as indicated. | All |  |
| 15 | Provide logistical information and instructions for coitus, if applicable. Offer panty liners  | All |  |
| 16 | Provide study product and study product use instructions* 1 applicator for Visits 3a, 4a, 5a, 6a
* 2 applicators for Visit 7a

Complete Study Product Accountability CRF. | All |  |
| 17 | Schedule next visit, if applicable | All |  |
| 18 | Provide reimbursement | All |  |
| Visits 3b, 4b, 5b, 6b, 7bNOTE: Visits 5b and 6b will occur approximately 1 day after Visits 5a and 6a, respectively. Procedures performed during visits 5b and 6b should be bracketed, initialed, and dated to illustrate the different date. |
| 19 | Collect used applicator; collect unused applicator if anyUpdate Study Product Accountability CRF from previous visit. | All |  |
| 20 | Collect post coitus timing information from participant and record on the Visit Summary CRF. | Visits 3b, 5b, 7b |  |
| 21 | Conduct CASI Behavioral Questionnaire | Visits 3b, 4b, 5b, 6b, and 7b |  |
| 22 | Conduct CASI Exit Acceptability assessment and complete Study Exit CASI Tracking CRF | Visit 7b |  |
| 23 | If indicated, perform physical exam | Visit 7b |  |
| 24 | If indicated, collect urine for urine culture and/or NAAT for GC/CT | Visit 7b |  |
| 25 | 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 4b should occur at similar time point to Visit 3b. Sampling for Visit 6b should occur at similar time point to Visit 5b. | All |  |
| 26 | Provide and document counseling:* HIV pre-test counseling
* HIV/STI risk reduction counseling
 | Visit 7b |  |
| 27 | Collect 5 mL blood and perform and document HIV testing. | Visit 7b |  |
| 28 | Collect 10 mL blood for PK. | All |  |
| 29 | Document and report Adverse Events per site SOP | All |  |
| 30 | If indicated, refer for UTI/RTI/STI treatment per site SOP | Visit 7b |  |
| 31 | Provide contact information and instructions to report symptoms and/or request information before next visit | All |  |
| 32 | Schedule next visit, if indicated  | All |  |
| 33 | Provide reimbursement | All |  |
| 34 | Review and fax all required DataFax forms to SCHARP DataFax.**Visits 3a/3b, 4a/4b, 5a, 5b, 6a, 6b, 7a/7b:*** Visit Summary (Visits 3a/3b, 4a/4b, 5a, 5b, 6a, 6b, 7a/7b)
* Physical Exam (Visits 3a, 4a, 5a, 6a, 7a)
* Pelvic Exam (Visits 3b, 4b, 5b, 6b, 7b)
* Clinically-indicated Pelvic Exam (Visits 3a, 4a, 5a, 6a, 7a if indicated)
* STI Test Results (Visits 3a/3b (single form), 4a/4b (single form), 5a, 5b, 6a, 6b, 7a/7b (single form))
* Pharmacokinetics (Visits 3b, 4b, 5b, 6b, 7b)
* Study Product Accountability (Visits 3a, 4a, 5a, 6a, 7a)
* Laboratory Results (Visit 7b)
* Study Exit CASI Tracking (Visit 7b)
* End of Study Inventory (Visit 7b)
* Termination (Visit 7b) (for female and male participants)
* Pelvic Exam Diagrams (non-DataFax) (Visits 3b, 4b, 5b, 6b, 7b) (Visits 3a, 4a, 5a, 6a, 7a if indicated)
* LDMS Specimen Tracking Sheet (non-DataFax) (Visits 3b, 4b, 5b, 6b, 7b)
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