**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 and Male Final Visit Procedures** | | **Female Ppt** | **Male Ppt** |
| --- | --- | --- | --- |
| 1 | Confirm identity and PTID |  |  |
| 2 | Check for co-enrollment in other studies:   * NOT enrolled in another study ==> CONTINUE * Enrolled in another study ==> Consult PSRT |  |  |
| 3 | Review elements of informed consent as needed |  |  |
| 4 | Review/update locator information |  |  |
| 5 | Collect used applicators; collect unused study product if any  Update Study Product Accountability CRF from previous visit. |  | NA |
| 6 | Conduct CASI Exit Acceptability assessment.  Complete Study Exit CASI Tracking CRF. |  |  |
| 7 | Conduct CASI Behavioral Questionnaire (women only) |  | NA |
| 8 | Collect follow-up medical/medications history: review/update AE Log, and Concomitant Medications Log CRFs. |  |  |
| 9 | Provide and document counseling:   * HIV pre-test counseling * HIV/STI risk reduction counseling |  |  |
| 10 | Collect 5 mL blood and perform and document HIV testing. |  |  |
| 11 | Collect 10 mL blood for pK. |  | NA |
| 12 | Collect urine (15-60 mL) and send to lab for urine hCG (FEMALE ONLY). If indicated, NAAT for GC/CT and urine culture |  |  |
| 13 | Perform and document modified physical exam. Complete Physical Exam CRF for female participants and Physical Exam – Male form (non-DataFax) for male participants. |  |  |
| 14 | Perform and document pelvic exam per Pelvic Exam Checklist (FEMALE ONLY) Complete a new Pelvic Exam Diagrams and Pelvic Exam CRF  hr min  \_\_\_\_\_\_\_: \_\_\_\_\_\_\_  Note: Sampling for Visit 9 should occur at similar time point to Visit 7b. |  | NA |
| 15 | Perform and document genital exam (MALE ONLY):  Complete Genital Exam form (non-DataFax).  General inspection via naked eye and if necessary, hand=held magnifying glass of the following:   * Internal and external foreskin (if present) * Entire penile surface * Shaft * Glans * Urethral meatus * Scrotum * Inguinal lymph nodes (right and left) | NA |  |
| 16 | If STI/RTI/UTI is diagnosed, provide treatment. |  |  |
| 17 | Provide and explain all available findings and results. Refer for findings as indicated. |  |  |
| 18 | Document and report Adverse Events per site SOP |  |  |
| 19 | Provide contact information |  |  |
| 20 | Schedule next visit, if applicable to provide final laboratory test results |  |  |
| 21 | Provide reimbursement |  |  |
| 22 | Review and fax all required DataFax forms to SCHARP DataFax.  **Visit 9:**   * Visit Summary * Physical Exam * Pelvic Exam * STI Test Results * Pharmacokinetics * Laboratory Results * Group 2 – Participant-reported Dosing * Study Exit CASI Tracking * End of Study Inventory * Termination (for male and female participants) * Pelvic Exam Diagrams (non-DataFax) * Genital Exam – Male (non-DataFax) * Physical Exam – Male (non-DataFax) * LDMS Specimen Tracking Sheet (non-DataFax) |  |  |