**Instructions:** Complete staff initials next to procedures completed for both female and male participants. Do not initial for other staff members. If other staff members are not available to initial checklist items themselves, enter, initial, and date a note on the checklist documenting who completed the procedure, e.g., “done by {name}” or “done by nurse.” If a procedure listed on the checklist is not performed, enter “ND” for “not done” or “NA” for “not applicable” beside the item and record the reason why (if not self-explanatory); initial and date this entry.

| **GROUP 1 Enrollment** **Procedures** | | **Female ppt** | **Male ppt** |
| --- | --- | --- | --- |
| 1 | Confirm identity and PTID and whether female participant’s menses ended 2-12 days ago. *[If on menses, reschedule enrollment within the screening window, if possible]* |  |  |
| 2 | Check for co-enrollment in other studies:   * NOT enrolled in another study ==> CONTINUE. * Enrolled in another study ==> STOP. ASSESS ELIGIBILTY. |  |  |
| 3 | Confirm couple is within 30-day screening window   * WITHIN 30 days from screening visit ==> CONTINUE. * OUTSIDE 30 days from screening visit ==> STOP. Not eligible to enroll during this screening attempt ==> If willing, schedule for rescreening (Note: Only two screening attempts allowed per Group) |  |  |
| 4 | If couple is re-enrolling into the alternate group, confirm couple is within 30-90 day window from last study visit   * Couple is WITHIN 30-90 days from last visit ==> CONTINUE   + Conduct Informed Consent for Group 1   + Assign new PTIDs for couple * Couple is OUTSIDE 90 days from last visit ==> STOP. Not eligible to enroll ==> If willing, schedule for rescreening (Note: Only two screening attempts allowed per Group) * Couple is WITHIN window but it has been more than 42 days since last visit ==> PAUSE. Both the male and female participant are required to undergo HIV, Syphilis and GC/CT testing. Once results are available, and negative, reschedule couple to return to clinic to continue with Enrollment procedures.   NOTE: Sites must consult the PSRT for guidance on re-enrolling any participants who are currently experiencing a Grade 3 or 4 AE, regardless of relationship, at the time of enrollment. If participants have a Grade 3 or 4 at time of enrollment, PAUSE procedures and reschedule couple to return once a PSRT response is received. |  |  |
| 5 | Provide and explain all prior screening test results |  |  |
| 6 | Provide and document HIV Post Test Counseling, if applicable |  |  |
| 7 | Provide and document modified risk reduction counseling |  |  |
| 8 | Review/update locator information and re-assess adequacy:   * Adequate locator information ==> CONTINUE. * Inadequate locator information ==> STOP. NOT ELIGIBLE. |  |  |
| 9 | Confirm behavioral protocol eligibility and document on Eligibility Checklist   * ELIGIBLE thus far ==> CONTINUE. * NOT ELIGIBLE ==> STOP. * Couple is re-enrolling in alternate group ==> confirm continued monogamy. No other behavioral eligibility is required. |  |  |
| 10 | Review/update baseline medical and medications history: review Pre-existing Conditions and Concomitant Medications Log CRFs. |  |  |
| 11 | Collect urine (15-60 mL) and send to lab for Urine hCG (FEMALE ONLY). If indicated, urine NAAT for GC/CT and urine culture |  | NA |
| 12 | Review study contraception requirements, and provide contraceptive counseling (FEMALE ONLY) |  | NA |
| 13 | Perform modified physical exam. Complete Physical Exam CRF for female participants. Physical exam for Male participant not required, however if an exam is indicated, complete the Physical Exam – Male form (non-DataFax) for male participants. |  | If Indicated |
| 14 | Perform and document pre-coital pelvic exam per Pelvic Exam Checklist. Complete a new Pelvic Exam Diagrams and Pelvic Exam CRF. |  | 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. REASSESS ELIGIBILTY. |  |  |
| 17 | Provide and explain all available findings and results. Refer for other findings as indicated. |  |  |
| 18 | Conduct confirmation and final determination of eligibility status by review/completion of Eligibility Checklist per site SOP.   * ELIGIBLE ==> CONTINUE * NOT ELIGIBLE ==> STOP. DO NOT ENROLL. ==> Pause and evaluate whether participant is:   + NOT ELIGIBLE but likely to meet eligibility criteria within this screening attempt ==> PAUSE ==> perform and document all clinically indicated procedures. Schedule another Enrollment Visit when participant is likely to be eligible.   + NOT ELIGIBLE and NOT likely to meet eligibility criteria within this screening attempt ==> STOP. Provide clinical management as needed. * NA ==> Couple is re-enrolling in alternate group, CONTINUE. |  |  |
| 19 | Verify participant eligibility by review of Eligibility Checklist (must be different staff member than step 18):   * ELIGIBLE ==> CONTINUE. Participant is now considered enrolled in study * NOT ELIGIBLE ==> STOP. DO NOT ENROLL. Provide clinical management as needed. * NA ==> Couple is re-enrolling in alternate group, CONTINUE. |  |  |
| 20 | Collect blood for plasma archive and send to lab   * 1 x 10 mL lavender top (EDTA) tube   NOTE: if couple is re-enrolling in alternate group, plasma archive is not required |  |  |
| 21 | Administer CASI Baseline Questionnaire (Both Male and Female).  NOTE: if couple is re-enrolling in alternate group, CASE Baseline Questionnaire is not required |  |  |
| 22 | Administer CASI Behavioral Questionnaire (Female Only) |  | NA |
| 23 | Instruct male participants to complete self-administered Male Behavioral Questions (MALE ONLY)  Transcribe onto Male Practices – Group 1 CRF. | NA |  |
| 24 | Provide logistical information and instructions for coitus.   * Offer panty liners. |  |  |
| 25 | Provide contact information and instructions to report symptoms and/or request information before next visit (MALE ONLY) | NA |  |
| 26 | Schedule next visit, if applicable |  |  |
| 27 | Provide reimbursement |  |  |
| POST-COITUS PROCEDURES (WOMEN ONLY/VISIT 2b) | | |  | |  |
| 28 | Collect post coitus timing information from participant and record on the Visit Summary CRF. |  | NA |
| 29 | Approximately 2 hours after coitus, perform pelvic exam per pelvic exam checklist. Complete a new Pelvic Exam Diagrams and Clinically-indicated Pelvic Exam CRF. |  | NA |
| 30 | Document and report Adverse Events per site SOP |  | If indicated |
| 31 | Provide contact information and instructions to report symptoms and/or request information before next visit |  | NA |
| 32 | Schedule next visit |  | NA |
| 33 | Provide reimbursement |  | NA |
| 34 | For enrolled participants, QC and then Fax all required DataFax forms from the Screening and Enrollment visits to SCHARP DataFax.  **From Screening Visit:**   * Demographics (for female and male participants) * Physical Exam * Pelvic Exam * Laboratory Results * STI Test Results * Pharmacokinetics * Family Planning * Pelvic Exam Diagrams (non-DataFax) * Screening Menstrual History (non-DataFax) * Genital Exam – Male (non-DataFax) * Physical Exam – Male (non-DataFax) * LDMS Specimen Tracking Sheet (non-DataFax)   **Enrollment Visit:**   * Enrollment (for female and male participants) * Physical Exam * Pelvic Exam (Visit 2a) * Pelvic Exam - Clinically-indicated (Visit 2b) * STI Test Results * Pharmacokinetics * Family Planning * Male Practices – Group 1 * Pelvic Exam Diagrams (non-DataFax) * Pelvic Exam Diagrams (non-DataFax) (for 2nd exam) * Genital Exam – Male (non-DataFax) * Physical Exam – Male (non-DataFax), if indicated * LDMS Specimen Tracking Sheet (non-DataFax)   **Log CRFs**   * Pre-existing Conditions * Concomitant Medications Log (for female and male participants) |  |  |