**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 1 MALE Follow-up Procedures**  | **Required at visits:** | **Staff Initials** |
| --- | --- | --- |
| Gel Provision Visits (3a, 5a, 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 and 5a |  |
| 6 | Instruct participant to complete self-administered Male Behavioral Questions. Transcribe onto Male Practices Group 1- CRF | All |  |
| 7 | Collect follow-up medical/medications history: review/update AE Log, and Concomitant Medications Log CRFs.  | All |  |
| 8 | Provide modified HIV/STI risk reduction counseling | All |  |
| 9 | If indicated, collect urine for NAAT for GC/CT and urine culture | All |  |
| 10 | Perform and document modified physical exam. Complete Physical Exam – Male form (non-DataFax). | All |  |
| 11 | If indicated, perform and document genital exam | All |  |
| 12 | If STI/RTI/UTI is diagnosed, provide treatment. | All |  |
| 13 | Provide and explain all available findings and results. Refer for findings as indicated. | All |  |
| 14 | Provide logistical information and instructions for coitus.  | All |  |
| 15 | Schedule next visit, if applicable | All |  |
| 16 | Provide reimbursement | All |  |
| Post-Coitus Visit (ONLY 7b) |
| 17 | Conduct CASI Exit Acceptability assessment | Visit 7b |  |
| 18 | If indicated, perform physical exam | Visit 7b |  |
| 19 | If indicated, collect urine for urine culture and/or NAAT for GC/CT | Visit 7b |  |
| 20 | Perform and document genital exam: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)
 | Visit 7b |  |
| 21 | Provide and document counseling:* HIV pre-test counseling
* HIV/STI risk reduction counseling
 | Visit 7b |  |
| 22 | Collect 5 mL blood and perform and document HIV testing. | Visit 7b |  |
| 23 | Document and report Adverse Events per site SOP | Visit 7b |  |
| 24 | If indicated, refer for UTI/RTI/STI treatment per site SOP | Visit 7b |  |
| 25 | Provide contact information and instructions to report symptoms and/or request information  | Visit 7b |  |
| 26 | Schedule next visit, if indicated  | Visit 7b |  |
| 27 | Provide reimbursement | Visit 7b |  |
| 28 | Review and fax all required DataFax forms to SCHARP DataFax.**Visits 3a, 5a, 7a, 7b:*** Male Practices – Group 1 (Visits 3a, 5a, 7a)
* Physical Exam – Male (non-DataFax) (Visits 3a, 5a, 7a)
* Genital Exam - Male (non-DataFax) (Visit 7b)
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