**Instructions:** Enter staff initials next to each procedure completed. Do not initial procedures another staff member completed. If other staff members are not available to initial next to each procedure they completed themselves, add a note on the checklist documenting who completed the procedure initial, date this entry, e.g., “done by {staff initials}” 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..

| **Enrollment/Initiate Period 1 - Visit Checklist** | | | |
| --- | --- | --- | --- |
| **Procedure** | | **Staff Initials** | **Comments:** |
|  | **Confirm identity and PTID.** |  |  |
|  | **Check for co-enrollment in other studies:**   * NOT enrolled in another study ==> CONTINUE. * Enrolled in another study ==> STOP. NOT ELIGIBLE. |  |  |
|  | **Confirm participant 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)   *\* Consult the SSP Section 5 for all exceptions to rescreening requirements.* |  |  |
|  | **Review/update locator information and re-assess adequacy:**   * Adequate locator information ==> CONTINUE. * Inadequate locator information ==> STOP. NOT ELIGIBLE. |  |  |
|  | **Review informed consent and study procedures including specimen storage, IDPI and, where applicable, rectal fluid/tissue subset. Confirm participant is still willing to participate**:   * Willing to participate in main study ==> CONTINUE. * NOT willing to participate in main study ==> STOP. NOT ELIGIBLE. |  |  |
|  | **Provide available test results from screening visit.** **Treat and/or refer for care as required.** |  |  |
|  | **Administer Enrollment Behavioral Eligibility CRF.**   * ELIGIBLE thus far ==> CONTINUE. * NOT ELIGIBLE ==> STOP. |  |  |
|  | **Administer Baseline CASI Questionnaire.** |  |  |
|  | **Provide HIV pre-test counseling, per site HIV testing/counseling/support/ referral SOP and HIV and Risk Reduction Counseling Worksheet, if applicable.** |  |  |
|  | **Collect blood samples for:**   * HIV serology \_\_\_ mL [tube type] * Plasma Archive \_\_\_ mL [tube type] (Sites can collect at this time-point if blood collection for HIV done via Venipuncture) **Note:** Plasma archive must be collected prior to randomization.   If clinically indicated:   * AST, ALT \_\_\_ mL [tube type] * CBC with differentials and platelets \_\_\_ mL [tube type] * Creatinine \_\_\_ mL [tube type] * Syphilis RPR \_\_\_ mL [tube type]   Transcribe results onto Safety Laboratory Results CRF once available. |  |  |
|  | **Provide test results and post-test counseling, including HIV/STI risk reduction counseling and provision of condoms. Provide referrals if needed/requested.**  **Transcribe results onto HIV Results CRF.**   * If [both] test[s] negative ⇒ UNINFECTED ⇒ ELIGIBLE ⇒ CONTINUE. * If [both] test[s] positive ⇒ INFECTED ⇒ STOP. NOT ELIGIBLE. * [If one test positive and one test negative ⇒ DISCORDANT ⇒ STOP ⇒ WB is required ⇒ PERFORM ADDITIONAL DIAGNOSTIC TESTING PER LOCAL STANDARD OF CARE.] * Offer HIV counseling and testing for partner(s). |  |  |
|  | **Administer Hepatitis B vaccine if indicated and participant consents;** document vaccination (or participant refusal) per site SOPs, if indicated. If given, record the vaccination as a separate entry on the Concomitant Medications Log |  |  |
|  | *[Bangkok and Pittsburgh sites only: insert the following language]*  **Rectal biopsy/fluid procedural counseling** |  |  |
|  | **Review/update Baseline Medical History Questions** form as needed**.** |  |  |
|  | **Review medications history and update Concomitant Medications Log CRF as needed.** |  |  |
|  | **Perform physical exam**. **Complete Abbreviated Physical Exam CRF.** |  |  |
|  | **Collect urine** (15-60 mL), if clinically indicated for:   * Dipstick urinalysis * NAAT for GC/CT |  |  |
|  | **Perform and document anorectal exam. Collect rectal samples (See Rectal Exam Checklist).** |  |  |
|  | **If STI/RTI/UTI is diagnosed ⇒ STOP. NOT ELIGIBLE.**   * Provide or refer for treatment/care.   **Note:** If not eligible to enroll ==> If willing, schedule for rescreening (Note: Only two screening attempts allowed). *Consult the SSP Section 5 for all exceptions to rescreening requirements.* |  |  |
|  | **Provide and explain all available findings and results. Refer for findings as indicated.** |  |  |
|  | **Transcribe all ongoing medical conditions on the Baseline Medical History Questions to the Pre-Existing Conditions form.** |  |  |
|  | **Conduct confirmation and final determination of eligibility status by review/completion of Eligibility Checklist.**   * ELIGIBLE thus far ==> CONTINUE ==> proceed to eligibility verification * NOT ELIGIBLE ==> STOP. DO NOT RANDOMIZE. ==> Provide clinical management or referrals, as needed. Complete and fax Eligibility Criteria CRF. |  |  |
|  | **Verify participant eligibility by review of column #2 of Eligibility Checklist (must be different staff member than step 23):**   * ELIGIBLE thus far ==> CONTINUE * NOT ELIGIBLE ==> STOP. DO NOT RANDOMIZE. Provide appropriate care/support or referrals, as needed. Complete and fax Eligibility Criteria CRF. |  |  |
|  | **If not already collected in step 10, collect blood for plasma archive and send to lab.** *[Note: if site is not doing finger stick, collect this sample with blood for HIV serology, edit checklist as appropriate]* |  |  |
|  | **Assign next sequential Randomization Envelope to participant per site SOPs. Complete a new row on the Randomization Envelope Tracking Record. PARTICIPANT IS NOW ENROLLED IN THE STUDY.** |  |  |
|  | **Open the assigned envelope and confirm that the envelope number printed on the MTN-017 Randomization Document contained in the envelope corresponds with the number on the outside of the envelope.** |  |  |
|  | **Complete the MTN-017 prescription that corresponds to the participant’s first study period (Oral, Daily Rectal, or RAI Rectal) per study randomization. Deliver prescription to pharmacy according to site SOP.** |  |  |
|  | **Provide product, relevant product use instructions, and lubricant, if indicated.**  **Note:** The staff person providing product use instructions should NOT be the same person who provides participant-centered product adherence counseling.  *[Bangkok and Pittsburgh sites only: participants whose first regimen is rectal gel (daily or RAI-associated use) will be instructed to start product use 72 hours (3 days) after the enrollment visit.]* |  |  |
|  | **Complete Product Dispensation and Return CRF.** |  |  |
|  | **Provide protocol adherence counseling. Advise participant to record date/time of last dose prior to next visit.** Document in chart notes [or site-specific source document].  **Note:** The staff person providing protocol adherence counseling should NOT be the same person who provides participant-centered product adherence counseling. |  |  |
|  | **Observe participants first dose (tablet) or simulation of first (empty gel applicator).**   * If participant initiating daily tablet, the first dose should be directly observed by study staff. * If participant initiating daily rectal gel, first insertion or simulation of first insertion should be performed in a private space, with staff standing by in case participant needs assistance. * If participant initiating RAI rectal gel, simulation of first insertion should be done in a private space, with staff standing by in case participant needs assistance. |  |  |
|  | **Provide Participant-Centered Product Adherence Counseling.** Document in chart notes [or site-specific source document].  **Note:** The staff person providing participant-centered product adherence counseling should NOT be the same staff person who provided product use instructions and protocol adherence counseling. |  |  |
|  | **Provide SMS training, using cell phone that participant will use throughout the study. Give participant SMS Instruction Card to take home with relevant information filled in.** |  |  |
|  | **Generate follow-up visit schedule. Advise him/her of potential length of the next visit.** Provide contact information and instructions to report symptoms and/or request information, counseling, study product, or condoms and lubricant, if indicated, before next visit. |  |  |
|  | **Perform QC1: while participant is still present, review the following for completion:**   * Enrollment Behavioral Eligibility * Eligibility Checklist * Enrollment Visit LDMS Specimen Tracking Sheet(s) (non-DataFax) * Pre-existing Conditions CRF |  |  |
|  | **Update co-enrollment database, Screening and Enrollment Log, and/or [site-specific tracking documents]. Generate participant visit calendar if not done already.** |  |  |
|  | **Remind the participant that s/he will be contacted via phone at the following times:**   * 48-72 hours (2-3 days) from the date of expected product initiation, and: * 2 weeks after the date of expected product initiation * If no SMS messages have been received by the system in a 48 hour period |  |  |
|  | **Provide reimbursement** |  |  |
| ***AFTER VISIT PROCEDURES*** | | | |
|  | **Upload audio file from Adherence Counseling Session to Atlas web site.** |  |  |
|  | **For enrolled participants, QC and then Fax all required DataFax forms from the Screening and Enrollment visits to SCHARP DataFax.**  **From Screening Visit:**   * Demographics * Anorectal Exam * Abbreviated Physical Exam * HIV Results * Safety Laboratory Results * STI Test Results   **Enrollment Visit:**   * Enrollment * Eligibility Criteria * Anorectal Exam * Abbreviated Physical Exam * HIV Results * Product Dispensation and Return * Rectal Biopsy/Fluid Subset Specimens, if applicable * Specimen Storage   **Log CRFs**   * Pre-existing Conditions * Concomitant Medications Log   If participant not enrolled for this screening attempt, complete and fax Eligibility Criteria CRF only to SCHARP DataFax. |  |  |

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| **Additional Notes/Comments/Referrals:** | |
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