| **Screening Visit Checklist** | | | |
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| **Procedures** | | **Staff Initials** | **Comments:** |
|  | **Verify identity and age.**   * ≥ 18 years of age at screening ==> CONTINUE. * < 18 years of age at screening ==>STOP. NOT ELIGIBLE. |  |  |
|  | **Check for co-enrollment in other studies or prior screening/enrollment into MTN-017:**   * NOT currently enrolled in another study, including MTN-017 ==> CONTINUE. * Currently enrolled in another study ==> STOP. NOT ELIGIBLE. |  |  |
|  | **Determine screening attempt (Verify if MTN-017 PTID has previously been assigned)**   * First attempt ==> Document recruitment source, CONTINUE. * \*Second attempt ==> CONTINUE.   *\* Consult the SSP Section 5 for all exceptions to rescreening requirements.* |  |  |
|  | **Obtain written informed consent for screening and enrollment, specimen storage and future testing, and IDPI. [Bangkok and Pittsburgh sites only: Obtain informed consent for Extra Samples Group]**   * Willing and able to provide written informed consent for screening and enrollment ==> CONTINUE. * NOT willing and able to provide written informed consent for screening and enrollment ==> STOP. NOT ELIGIBLE. |  |  |
|  | **Assign PTID (if not done during a previous screening attempt).** Record on  Screening and Enrollment Log. |  |  |
|  | **Obtain locator information using site-specific form**, per site eligibility determination SOP.   * + Inadequate locator information ==> STOP. NOT ELIGIBLE. * Adequate locator information ==> CONTINUE. |  |  |
|  | **Administer Demographics CRF** |  |  |
|  | **Administer Screening Behavioral Eligibility CRF**   * NOT ELIGIBLE ==> STOP. * ELIGIBLE thus far ==> CONTINUE. |  |  |
|  | **Administer SMS Readiness Assessment** |  |  |
|  | **Collect urine** (15-60 mL). Complete [*add site-specific laboratory testing source document]* upon receipt of lab test results:   * Dipstick urinalysis. * NAAT for GC/CT. |  |  |
|  | **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] * CBC with differential and platelets\_\_\_ mL [tube type] * Chemistries (Creatinine, AST/ALT). Note: Creatinine clearance must be calculated \_\_\_ mL [tube type] * [syphilis, HSV 1-2, HBsAb, HBsAg, Anti-HCV]\_\_\_ mL [tube type] for   *[Bangkok and Pittsburgh sites only: insert the following language]*   * Mucosal Biopsy Subset Only: \_\_\_ mL [tube type] for [*coagulation(PT/INR)*]   Transcribe results onto Safety Laboratory Results CRF once available. |  |  |
|  | **Perform HIV testing per site SOPs.** |  |  |
|  | **Provide test results and post-test counseling, including HIV/STI risk reduction counseling and provision of condoms:**   * 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 ⇒ ⇒ NOT ELIGIBLE⇒ PERFORM ADDITIONAL DIAGNOSTIC TESTING PER LOCAL STANDARD OF CARE.]   Provide referrals if needed/requested.   * Offer HIV counseling and testing for partner(s). * Transcribe results onto HIV Results CRF. |  |  |
|  | **Collect baseline medical and medication history**. Complete Baseline Medical History Questions form and Pre-existing Conditions and Concomitant Medications Log CRFs. |  |  |
|  | **Perform physical examination**. Complete the Abbreviated Physical Exam CRF. |  |  |
|  | **Perform perianal visual inspection. Complete item #1 of the Anorectal Exam CRF.** |  |  |
|  | **Collect the rectal swab for HSV detection**, if indicated. |  |  |
|  | **Perform a digital examination**. **Complete item #2 of the Anorectal Exam CRF.** |  |  |
|  | **Prepare anoscope in preparation for specimen collection per SSP section 8.5.1.** |  |  |
|  | **Collect the rectal swab for GC/CT NAAT testing** |  |  |
|  | **Remove anoscope.** |  |  |
|  | **Evaluate any abnormal findings. Explain all available test results and exam findings available.** |  |  |
|  | **Document findings on the Anorectal Exam CRF.** |  |  |
|  | **If STI/RTI/UTI or other abnormal findings are identified**, provide or refer for treatment/care as needed. |  |  |
|  | *[Bangkok and Pittsburgh sites only: insert the following language]*  **Rectal biopsy/fluid procedural counseling** |  |  |
|  | **Determine last possible enrollment date for this screening attempt (up to 30 days from screening visit)**:    (DD/MMM/YY) |  |  |
|  | **Schedule next visit taking into consideration the length of time required to receive lab results. Advise participant of potential length of next visit. Remind participant to bring cell phone to next visit.** |  |  |
|  | **Provide study informational material, site contact information, and instructions to contact the site for additional information and/or counseling if needed before the next visit**: *[add site-specific list if desired]* |  |  |
|  | **Review the following documentation while participant is still present:**   * Review interviewer-administered CRFs to ensure all items are complete/accurate (Demographics, Screening Behavioral Eligibility) * Review Abbreviated Physical Exam and Anorectal Exam CRF; ensure all findings are clearly documented * Review Baseline Medical History Questions, Pre-existing Conditions, and Con Meds Log to ensure all conditions and medications are captured * Briefly review chart notes to ensure it is complete and accurate thus far |  |  |
|  | **Provide reimbursement for coming to the clinic** |  |  |
|  | **Complete ‘screening visit’ column of Eligibility Checklist and assess participant’s current eligibility status.**   * ELIGIBLE thus far →CONTINUE. * NOT ELIGIBLE → STOP. |  |  |
|  | **Complete and assemble all CRFs from the Screening Visit. Do not fax until participant has enrolled (randomized) into the study.** |  |  |
|  | **Note:** If participant will not proceed to Enrollment, complete and fax Eligibility Criteria CRF. |  |  |
| **Additional Notes/Comments/Referrals:** | | | |
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