| **Screening Visit Checklist (Visit 1.0)** | | | |
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| **Procedures** | | **Staff**  **Initials** | **Comments** |
|  | Confirm identity and age per site SOPs.   * > 18 and < 45 years of age at screening ==> CONTINUE. * <18 or > 45 ==> STOP. NOT ELIGIBLE. |  |  |
|  | Check for co-enrollment in other studies:   * NOT enrolled in another study ⇒ CONTINUE. * Enrolled in another study ⇒ STOP. ASSESS ELIGIBILITY. |  |  |
|  | Determine screening attempt (verify if MTN-030 PTID has previously been assigned). |  |  |
|  | Explain, conduct, and document the informed consent process for potential participant. Complete Informed Consent Coversheet andcomprehension assessment tool, per site SOP:   * Willing and able to provide written informed consent ⇒ CONTINUE. * NOT willing and able to provide written informed consent ⇒ STOP. NOT ELIGIBLE. |  |  |
|  | Assign a PTID (if not done during a previous screening attempt) and enter onto Screening and Enrollment Log and PTID Name Linkage Log. |  |  |
|  | Explain procedures to be performed at today’s visit. |  |  |
|  | Document behavioral eligibility on Screening Behavioral Eligibility Worksheet.   * ELIGIBLE thus far ==> CONTINUE. * NOT ELIGIBLE ==> STOP. |  |  |
|  | Administer Demographics CRF. |  |  |
|  | Obtain locator information and determine adequacy per site SOPs:   * Adequate locator information ⇒ CONTINUE. * Inadequate locator information ⇒ PAUSE and re-assess. |  |  |
|  | Assess whether participant has a mobile phone, with SMS capabilities, available for use during study participation. |  |  |
|  | Collect (15-60 mL) urine. Perform pregnancy test and document on [add site-specific laboratory testing source document, or Pregnancy Test CRF if source]:   * NOT pregnant ⇒ CONTINUE. * Pregnant ⇒ STOP. NOT ELIGIBLE. |  |  |
|  | If indicated, perform dipstick urinalysis and/or culture per site SOP. Complete [add site-specific laboratory testing source document] upon receipt of lab test results.  NOTE: If participant is symptomatic and is diagnosed with a UTI, she must complete  treatment and all symptoms must resolve before she is eligible for enrollment. |  |  |
|  | Provide and document HIV pre-test and HIV/STI risk reduction counseling using Pre/Post Test and Risk Reduction Counseling Worksheet. |  |  |
|  | Collect blood:  Sites to tailor this item to reflect site-specific tube types and volumes.   * X x 6 mL lavender top (EDTA) tube * X x 5 mL red top (no additive) tube * X x 10 mL red top (no additive) tube |  |  |
|  | Perform HIV-1 test(s) and document result(s) on [add site-specific laboratory testing source document, or HIV Tests CRF if source]. |  |  |
|  | Order required blood tests:   * Serum creatinine, AST, ALT * CBC with platelets and differential * Syphilis serology |  |  |
|  | Provide HIV test results and post-test counseling, including:   * Referrals if needed/requested * HIV counseling and testing for partner(s), if requested * Condoms, if indicated |  |  |
|  | Collect baseline medical, menstrual, and medications history: document on Baseline Medical History Questions Sheet, Screening Menstrual History CRF, Baseline Medical History (Summary, and Log if applicable) CRF(s), and the Concomitant Medications (Summary, and Log if applicable) CRF(s) as needed.  Note: Determine if participant has contraindication to progestin-only contraceptive method as defined by category 3 or 4 CDC criteria. |  |  |
|  | Determine current contraceptive method, review study contraception requirements, and document per site SOPs. |  |  |
|  | Obtain vitals and document on [add site-specific source document, or Vital Signs CRF if source]. |  |  |
|  | Perform full physical exam– document on [add site-specific source document, or Physical Exam CRF if source].   * BMI < 35 kg/m2 ⇒ CONTINUE. * BMI > 35 kg/m2 ⇒ STOP. INELIGIBLE. |  |  |
|  | Perform and document pelvic exam per Pelvic Exam Checklist. |  |  |
|  | Determine whether participant has current UTI/RTI/STI:   * No condition requiring treatment ⇒ CONTINUE. * UTI/RTI/STI ⇒ STOP. MAY BE INELIGIBLE.   NOTE: If participant is symptomatic and is diagnosed with a UTI/RTI, she must complete treatment and all symptoms must resolve before she is eligible for enrollment. If participant is diagnosed with an STI requiring treatment, she is ineligible. |  |  |
|  | Evaluate any abnormal findings. Provide and explain all available findings and results. If STI/RTI/UTI is diagnosed, provide or refer for treatment. Document provision of results, treatment and/or referrals in chart notes. |  |  |
|  | Perform QC1 review while participant is still present:   * Review this visit checklist and pelvic exam checklist to ensure all required procedures were completed. * Review [add site-specific pelvic exam, vital signs, and physical exam source documents, or Pelvic Exam Diagrams, Pelvic Exam CRF, Vital Signs CRF and/or Physical Exam CRF if source] to ensure all findings are clearly documented. * Review Screening Menstrual History CRF, Baseline Medical History Questions, Baseline Medical History Log CRF, and Concomitant Medications Log CRF to ensure all conditions and medications are captured consistently. * Briefly review Demographics CRF, Screening Behavioral Eligibility Worksheet, and chart notes to ensure completeness and accuracy. |  |  |
|  | Provide contact information, condoms (as needed) and instructions to contact the site for additional information and/or counseling if needed before the next visit. |  |  |
|  | Provide reimbursement. |  |  |
|  | Schedule Enrollment Visit so that participant menses does not occur during study participation (at a minimum, ensure menses does not coincide with 14 days of VR use). Determine last possible enrollment date for this screening attempt:    DD MON YY |  |  |
|  | If participant will proceed to Enrollment, complete the Eligibility Checklist, Eligibility Criteria CRF, and if applicable, the Inclusion Criteria CRF and/or Exclusion Criteria CRF, at the Enrollment Visit.  For failed screening attempts, the only CRFs that require completion are the Eligibility Criteria CRF, as well as the Inclusion Criteria CRF and/or Exclusion Criteria CRF as applicable. Other CRFs that were completed during the failed screening attempt may remain in the study database, and will not undergo QC review. |  |  |
|  | For successful screening attempts, ensure that data is entered into the study database (and perform QC2 review, if applicable) for the following required CRFs:   * Demographics * Concomitant Medications Summary * Concomitant Medications Log (if medications are reported) * Screening Menstrual History * Baseline Medical History Summary * Baseline Medical History Log (if pre-existing conditions are reported) * Pelvic Exam * Vital Signs * Physical Exam * Local Laboratory Results * Hematology * STI Tests * Pregnancy Test * HIV Tests |  |  |