| **Enrollment Visit (Visit 2.0) Checklist** | | | |
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| **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 45-day screening window   * WITHIN 45 days from screening visit ==> CONTINUE. * OUTSIDE 45 days from screening visit ==> STOP. Not eligible to enroll |  |  |
|  | Review/update locator information using site-specific form. Re-assess adequacy:   * Adequate locator information ==> CONTINUE. * Inadequate locator information ==> STOP. NOT ELIGIBLE. |  |  |
|  | Review elements of informed consent. Explain procedures to be performed at today’s visit. Confirm participant is still willing to participate:   * Willing to participate ==> CONTINUE. * NOT willing to participate==> STOP. NOT ELIGIBLE. |  |  |
|  | Assess participant behavioral eligibility using the Enrollment Behavioral Eligibility Worksheet   * ELIGIBLE thus far ==> CONTINUE * NOT ELIGIBLE but likely to meet eligibility criteria within this screening attempt ==> PAUSE ==> Re-schedule Enrollment Visit when participant is likely to be eligible. * NOT ELIGIBLE and NOT likely to meet eligibility criteria within this screening attempt ==> STOP |  |  |
|  | Provide available test results from screening visit. Treat and/or refer for care as required. |  |  |
|  | Administer Vaginal Practices CRF |  |  |
|  | Administer Baseline CASI Questionnaire |  |  |
|  | Provide and document the following on appropriate counseling worksheets or [*site-specific source document*]. Provide male condoms if needed.   * Protocol adherence counseling * HIV/STI risk reduction counseling (and male condom counseling if indicated) * HIV pre and post-test counseling if indicated |  |  |
|  | Review/update baseline medical and medications history, Baseline Medical History Questions Sheet, Pre-existing Conditions and Concomitant Medications Log CRFs. |  |  |
|  | If clinically indicated, collect (15-60 mL) urine.   * hCG (pregnancy testing) * Dipstick urinalysis and/or urine culture |  |  |
|  | If clinically indicated, review pregnancy test results:   * NOT pregnant ==> CONTINUE. * Pregnant ==> STOP. NOT ELIGIBLE. |  |  |
|  | Perform physical exam. Complete Physical Exam CRF. |  |  |
|  | Perform and document pelvic exam per Pelvic Exam Checklist. |  |  |
|  | If STI/RTI/UTI is diagnosed, provide treatment. Update Pre-existing Conditions and Concomitant Medications Log CRFs. Participant must complete treatment and be free of symptoms prior to enrollment. |  |  |
|  | Provide and explain all available findings and results. Refer for other findings as indicated. |  |  |
|  | Conduct confirmation and final determination of eligibility status by completing the ‘Enrollment Visit’ column of the Eligibility Checklist.   * ELIGIBLE thus far ==> CONTINUE ==> proceed to eligibility verification * NOT ELIGIBLE ==> STOP. DO NOT RANDOMIZE.   If participant will proceed to Enrollment, complete Eligibility Criteria CRF. |  |  |
|  | Collect blood for:   * Plasma Archive [10 mL]   Note: Plasma archive must be collected prior to randomization.  If clinically indicated:  **Testing is based on local lab requirements; tailor this item to reflect site-specific tube type and volume.**   * HIV serology * Serum Chemistries * CBC with platelets   If indicated, review HIV test results:   * HIV negative ==> CONTINUE. * HIV positive ==> STOP. NOT ELIGIBLE.   Document results on Enrollment, Safety Laboratory Results and HIV Results CRFs if indicated. |  |  |
|  | Randomize participant by assigning next randomization envelope. Complete Randomization Envelope Tracking Record. **PARTICIPANT IS NOW ENROLLED IN THE STUDY.** Complete prescription and send to pharmacy.  Was participant randomized to the in-depth interview?   * Yes * No |  |  |
|  | Review/provide ring insertion and removal instructions with participant, using visual aids as needed. Provide participant with vaginal ring for self-insertion and ask her to insert the ring. |  |  |
|  | Confirm placement of the vaginal ring through digital (bimanual) examination. |  |  |
|  | Document the provision of the vaginal ring to the participant using the Clinic Study Product Accountability Log and Ring Collection and Insertion CRF. |  |  |
|  | De-brief with participant about her first study product use experience *[document on Ring Use Adherence Key Messages Worksheet or site specific document]* |  |  |
|  | Provide ring use adherence counseling [*document on Ring Use Adherence Key Messages Worksheet or site specific document*] |  |  |
|  | Schedule 4 -Week Follow Up Visit and advise her of potential length of the visit. Provide contact information and instructions to report symptoms and/or request information, counseling, a new ring, or condoms before next visit. |  |  |
|  | If needed, provide study approved lubricant and Study-Approved Lubricant Use Log with instructions to complete if she chooses to use study-provided lubricant provided within the 72 hours prior to your next clinic visit. |  |  |
|  | Perform QC1: while participant is still present, review the following for completion:   * Eligibility Checklist * Pre-existing Conditions CRF |  |  |
|  | Document all stored specimens on the Specimen Storage CRF and LDMS Specimen Tracking Sheet |  |  |
|  | Update Screening and Enrollment Log and or site-specific tracking documents. Generate participant visit calendar if not done already. |  |  |
|  | Remind the participant that she will be contacted via phone in one week to follow up on any problems or concerns |  |  |
|  | Provide reimbursement |  |  |
|  | For enrolled participants, conduct QC2 and then Fax all required DataFax forms from the Screening and Enrollment visits to SCHARP DataFax.  **From Screening Visit:**   * Demographics * Pelvic Exam * Physical Exam * Safety Laboratory Results * STI Test Results * HIV Results * Pelvic Exam Diagrams (non-DataFax)   **Enrollment Visit:**   * Enrollment * Eligibility Criteria * Ring Collection and Insertion * Vaginal Practices * Physical Exam * Pelvic Exam * Specimen Storage * STI Test Results (if needed) * Pelvic Exam Diagrams (non-DataFax)   **Log CRFs**   * Pre-existing Conditions * Concomitant Medications Log   If participant not enrolled for this screening attempt, complete and fax Eligibility Criteria to SCHARP DataFax. |  |  |