| **MTN-032 PTID:** | | **Visit Date:** |
| --- | --- | --- |
|  |  | |
| **Initials** | **Procedures** | |
| **Preparation** | | |
|  | Audio-recorder checked (power supply, extra batteries, etc.) | |
|  | Supplies gathered: pen and stationery for note-taking, consent form, CRFs (PSF, DEM, BA), discussion guide, tools ~~opinion tool, stickers~~, refreshments (if applicable), reimbursement.  Discussion tools include:   * Phase 2 female participants: drug feedback over time tool, ~~and~~ opinion tool, and stickers * Phase 2 male participants: opinion tool, stickers & props (demonstration ring, vulva puppets & penis models) | |
|  | Female Participants - Verification of participant status (HIV status, adherence group) | |
|  | For female participants:   * Collect all available RD feedback for rings returned by participant (including final 3 months of participation and all quarterly averages, as applicable) * Complete MTN-032 Phase 2 RD Feedback Over Time Tool and attach to HOPE RD Feedback Over Time Tool | |
| **Participant Arrival, IC & Data Collection** | | |
|  | Greet participant and offer refreshments | |
|  | Confirm participant identity | |
|  | **INCLUSION CRITERIA - FEMALE PARTICIPANTS**  Confirm eligibility criteria:   * HOPE PTID included on Recruitment List from SCHARP   [*Inclusion criteria 1*]  For participants who did not acquire HIV while taking part in HOPE:   * Evidence of product dispensation for a minimum of three (3) consecutive months *[per site records; Inclusion criteria 4]*   For participants who acquired HIV while taking part in HOPE:   * Evidence of product dispensation in the month prior to the participant’s acquisition of HIV *[per site records; Inclusion criteria 5]* | |
| * ABOVE CRITERIA MET ⇒ ELIGIBLE ⇒ CONTINUE.   or   * ABOVE CRITERIA NOT MET ⇒ NOT ELIGIBLE ⇒ STOP, provide participant reimbursement and thank her for her time. Document in PSF and participant file notes. | |
|  | **INCLUSION CRITERIA - MALE PARTICIPANTS**  Confirm eligibility criteria:   * HOPE PTID for female partner included on Recruitment List from SCHARP   [*MP Inclusion criteria 1*]   * HOPE participant provided permission to contact this male partner *[according to HOPE study exit & permission to contact forms; MP Inclusion criteria 1 and 2]* * Is above the age of 18 at the time of study participation *[per participant ID or locator information; MP Inclusion criteria 5]* | |
|  | **INCLUSION CRITERIA - ALL PARTICIPANTS**  Explain, conduct, and document informed consent process per site SOPs:   * Willing and able to provide written informed consent ⇒ CONTINUE, have participant sign ICF, collect signed form, and offer a copy for participant to take home. [*Inclusion criteria 2 and 3 (female participants); Inclusion criteria 3 and 4 (male participants)*]   or   * NOT willing and able to provide written informed consent ⇒ STOP, provide participant reimbursement and thank her/him for her/his time. Document in PSF and participant file notes. | |
|  | **EXCLUSION CRITERIA – ALL PARTICIPANTS**   * Participant **DOES NOT** have any condition that, in the opinion of the IoR/designee, would preclude informed consent, make study participation unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives.   **ELIGIBLE ⇒ CONTINUE.**   * Participant has any condition that, in the opinion of the IoR/designee, would preclude informed consent, make study participation unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives.   [*Exclusion criteria 1*] ⇒ **NOT ELIGIBLE ⇒ STOP**. Document in Participant Status Form (PSF) and participant file notes. | |
|  | * Administer Demographic Information Form (DEM) * Administer Behavioral Assessment Form (BA) | |
|  | Review IDI ground rules:   * No right or wrong answers * Use pseudonyms when providing responses * Information shared remains confidential * Cell phone off | |
|  | Conduct Phase 2 IDI using appropriate female or male IDI guide | |
|  | **Female Participants** -- Complete section of PSF on results matching and trusting test (items 8 and 9) or record whether participant thinks her drug results match with how she used the ring and if she trusts the method used to test the rings in interview notes and record on PSF immediately following IDI. | |
|  | Thank and reimburse the participant | |
| **Post IDI (Immediately following IDI)** | | |
|  | Complete PSF | |
|  | Check audio recording to verify that the session was properly recorded. | |
|  | Expand notes and complete debriefing report | |
| **Comments**: *Initial and date all comments.* | | |