| **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, refreshments (if applicable), reimbursement | |
|  | Verification of participant status (HIV status, adherence level, and age group) | |
| **Participant Arrival, IC & Data Collection** | | |
|  | Greet participant and offer refreshments | |
|  | Confirm participant identity | |
|  | Confirm eligibility criteria:  ASPIRE PTID included on Recruitment List from SCHARP  [*Inclusion criteria 1, 4-7*]  Participant has been informed of her randomization assignment in ASPIRE  [*Inclusion criteria 1*]   * ELIGIBLE ⇒ CONTINUE.   or   * NOT ELIGIBLE ⇒ STOP, provide participant reimbursement and thank her for her time. Document in PSF and participant file notes. | |
|  | 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*]   or   * NOT willing and able to provide written informed consent ⇒ STOP, provide participant reimbursement and thank her for her time. Document in PSF and participant file notes. | |
|  | * 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 1 IDI Topic Guide. | |
|  | Complete drug level response section of PSF or note response to drug level discussion 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.* | | |