| **MTN-032 PTID:** | | **FGD No.:** | **Visit Date:** |
| --- | --- | --- | --- |
|  |  | | |
| **Initials** | **Procedures** | | |
| **Participant Arrival, IC & Data Collection** | | | |
|  | 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)   ❑ Present the participant with her individual drug level results from ASPIRE  ❑ Complete drug level response section of PSF or note response to drug level discussion on notes and record on PSF immediately following FGD. | | |
|  | Alert the participant that she will now be joining the FGD with participants who are in the same age group. | | |
| **Post FGD (Immediately following FGD)** | | | |
|  | Complete PSF | | |
| **Comments**: *Initial and date all comments.* | | | |