| **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.*       |