| **ASPIRE PTID:** | **FGD No.:** | **FGD Date:** |
| --- | --- | --- |
|  |
| **Initials** | **Procedures** |
| **Participant Arrival, IC & Data Collection** |
|  | Confirm participant identity, complete registration |
|  | ***[Sites with separate IC Process]*** Explain, conduct, and document informed consent process (on the IC coversheet) per site SOPs. *Note: IC can be obtained prior to the scheduled date of the FGD (e.g. at a participants PUEV). If IC has already been obtained, review key elements and confirm willingness to participate.* * 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.
* NOT willing and able to provide written informed consent ⇒ STOP, provide participant reimbursement, and thank her for her time. Document in participant file notes.
 |
|  | ***[Sites with integrated IC Process]*** Review key elements of qualitative IC and confirm willingness to participate. Document any questions/concerns in chart notes. * Willing and able to participate ⇒ CONTINUE
* NOT willing and able to participate ⇒ STOP, provide participant reimbursement, and thank her for her time. Document in participant file notes.
 |
|  | Confirm and document eligibility: ***For FGD:*** *HIV-negative participants who are enrolled in ASPIRE, have completed their PUEV, and have ever used study products in the 3 months prior to PUEV (per RCI, item 6). Participants may be excluded if they have any other 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 study objectives. Note that participants who have previously had an IDI (serial or single) should not be approached for FGDs.* * ELIGIBLE ⇒ CONTINUE.
* NOT ELIGIBLE ⇒ STOP. Document on Qualitative Participation Log (QPL)
 |
|  | Complete procedures as outlined on the FGD Group Visit Checklist.  |
| **Comments**: *Initial and date all comments.*         |