| **MTN-020 PTID:** | | **Visit Date:** |
| --- | --- | --- |
|  |  | |
| **Initials or NA** | **Procedures** | |
| **Preparation** | | |
|  | Type of Interview (mark one):   * Serial IDI, preselected on Q-PTRL: Interview number (circle): 1 2 3   Print/file email confirming QMT approval   * Serial IDI, identified as interesting case: Interview number (circle): 1 2 3 * Single IDI, HIV Seroconversion * Single IDI, Early Termination or Permanent Product Discontinuation | |
|  | Confirm and document eligibility for designated interview type *(NA for Serial IDI 2/3)*:  ***For Serial IDI:*** *Enrolled in ASPIRE, HIV-negative, and ever use of study product in the past 3 months (per RCI CRF, item 6) at the time of her first interview.*  ***For Single IDI:*** *Enrolled in ASPIRE and experiences at least one of the following: (1) HIV seroconversion, (2) permanent product discontinuation, or (3) withdraw from study participation.*  ***For All IDIs:*** *Does not have any condition for exclusion per IoR discretion.*   * ELIGIBLE ⇒ CONTINUE. * NOT ELIGIBLE ⇒ STOP. | |
|  | Audio-recorder checked (power supply, extra batteries, etc.) | |
|  | Venue confirmed and participant reminded of visit date/time/location. | |
|  | Supplies gathered: pen and stationery for note-taking, consent form, IDI guide, refreshments (if applicable), and reimbursement | |
|  | Review participant’s relevant study documentation from ASPIRE visits | |
|  | *(For serial IDI 2/3):* Review notes and/or Debrief Report(s) and/or transcript(s) from previous IDI(s) | |
| **Participant Arrival, IC & Data Collection** | | |
|  | Confirm participant identity, complete registration | |
|  | ***[Sites with separate IC Process]*** Explain, conduct, and document informed consent process per site SOPs. *(NA for Serial IDI 2/3):*   * 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. *(NA for Serial IDI 2/3)*:   * 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. | |
|  | Review IDI ground rules:   * No right or wrong answers * Use pseudonyms when providing responses * Information shared remains confidential * Cell phone off | |
|  | Administer the IDI guide | |
|  | Thank and reimburse the participant | |
| **Post IDI (Immediately following IDI)** | | |
|  | Check audio recording to verify that the session was properly recorded. Save/upload audio to FTP site. | |
|  | Expand interview notes | |
|  | Complete debrief report | |
| **Comments**: *Initial and date all comments.* | | |