| **MTN-042/DELIVER PTID:** | | | **Interview Date:** |
| --- | --- | --- | --- |
| **Initials and Date**  **or N/A** | **Procedures** | | |
| **IDI Preparation (at least 1 day prior to IDI visit)** | | | |
|  | Type of Interview (mark one):   * **IDI:** randomized by SCHARP * **Special case IDI (SCIDI):** nominated by site and approved by QMT, * Print/file email confirming QMT approval | | |
|  | Confirm and document eligibility for designated interview type:  ***For Randomized IDIs:***   * *Enrolled in DELIVER* * *Randomized to IDI per IDI Randomization Log* * *If in Cohort 1, participant had product dispensed at least 5 days before IDI visit or*   *if in Cohorts 2-4, participant had product dispensed at least 2 weeks before IDI visit*   * *Does not have any condition for exclusion per IoR discretion [participants who seroconvert or experience other adverse outcomes should be discussed on a case-by-case basis with the Management Team.]* * *Verbally agreed to participate in IDI during previous visit(s) or during phone contact*   ***For SCIDI:***   * *Enrolled in DELIVER* * *Confirmed eligible for SCIDI by QMT* * *Not a randomized IDI participant* * *Verbally agreed to participate in SCIDI during previous visit(s) or during phone contact*   *Mark final determination of eligibility for interview:*   * ELIGIBLE ⇒ CONTINUE checklist * NOT ELIGIBLE ⇒ STOP and document on QPL | | |
|  | Audio-recorder checked (power supply, extra batteries, etc.) | | |
|  | Venue confirmed and participant reminded of visit date/time/location at least one day before IDI. (Contact and attempted contact with participant recorded in chart notes or other site-specific contact log) | | |
|  | Supplies gathered: pen and stationery for note-taking, audio recorder, IDI guide, refreshments (if applicable), and reimbursement | | |
|  | Review participant’s product assignment to determine which questions will be asked from the IDI guide:   * Oral Truvada * DPV Ring | | |
| **Participant Arrival, IC & Data Collection** | | | |
|  | | Confirm participant identity per site SOPs | |
|  | | Review eligibility criteria above to ensure it is still accurate (if no longer eligible ⇒ STOP) | |
|  | | Review key elements of IC and confirm willingness to participate in the IDI. Document any questions/concerns in chart notes.   * Willing and able to participate ⇒ CONTINUE * NOT willing and able to participate ⇒ STOP and thank her for her time. Document in participant’s file and QPL. | |
|  | | Review IDI ground rules:   * No right or wrong answers * Use pseudonyms when providing responses * Information shared remains confidential * Cell phone off or on silent | | |
|  | | Administer the IDI guide, following guidelines outlined in SSP Section 14 Qualitative Component | | |
|  | | Thank and reimburse the participant | | |
| **Post IDI (Immediately following IDI)** | | | |
|  | | Document and refer any reported social harms, adverse events, or protocol deviations to DELIVER counselor or clinic staff per site SOP | | |
|  | | Check audio recording to verify that the session was properly recorded. Upload audio to hard drive and copy to CD. Label audio CD appropriately.  To certify, site should:   * Confirm the file size and/or length of the CD file is the same as electronic copy * Listen to the beginning of the audio file, (make sure it’s the right PTID and interview) and spot check middle and end to make sure it’s complete   Once above checks are done:   * If writing on the CD, should include filename (PTID, type of file, date of interview, etc.), the word “certified” and it should be initialed and dated * In addition to that if the site uses a “certify” stamp on a sticker on the CD they can do that with initials, date and filename * Store in participant’s file * Log the file name and location of each hard drive audio file | | |
|  | | Expand interview notes and store in participant’s file | | |
|  | | Complete debrief report (within 24 hours) | | |
|  | | Update QPL with date of IDI | | |
| **Comments**: *Initial and date all comments.*            \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | |