**Instructions:** Complete staff initials next to items completed. Do not initial for other staff members. If other staff members are not available to initial checklist items themselves, initial and date a note on the checklist documenting who completed the item, e.g., “done by {name}” or “done by nurse.” If an item listed on the checklist is not performed, enter “ND” for “Not Done” or “NA” for “Not Applicable” beside the item and record the reason why (if not self-explanatory); initial and date this entry. If any items are not completed on the date recorded above, ensure that the procedure date is included in the comments section.

| **Procedure** | | **Staff Initials** | **Comments:** |
| --- | --- | --- | --- |
| **Preparation (prior to participant arrival)** | | | |
|  | Ensure staff and site readiness:   * Check audio recorder and confirm that technical needs for screening participant education video are met (power supply, extra batteries, etc.) * Gather supplies: pen and stationery for note-taking, consent forms/coversheets/comprehension checklists, placebo products, CRFs (PSF, PD, DEM, BA, SH), interview guide, refreshments (if applicable), reimbursement *(See also SSP section 5.3 for details on visit prep)* * Confirm availability of IDI venue/room and complete visit reminders as outlined in site accrual SOPs |  |  |
| **Participant Arrival, IC and Data Collection** | | | |
|  | Complete participant registration, including confirmation of participant identity and age, per site SOP |  |  |
|  | Explain procedures to be performed at visit |  |  |
|  | Explain, conduct, and document informed consent process. Complete **Informed Consent Coversheet** and **Enrollment Informed Consent Comprehension Checklist**, per site SOP:   * Willing and able to provide written informed consent 🡪 CONTINUE. Have participant sign ICF, collect signed form, and offer a copy to participant [*Inclusion criterion 1*]   or   * NOT willing and/or able to provide written informed consent 🡪 STOP. Thank and provide reimbursement to participant. Record “N/A” as their PTID at the top of this checklist. |  |  |
|  | Inform the participant that an audio recording of her/his IDI will be retained for at least 3 years [or sites to include site-specific timeframe if IRB has different/longer requirements] following study completion, and that audio files will be stored securely and accessible only to designated study staff |  |  |
|  | Assign a unique Participant Identification (PTID) Number. Complete new entry on **Screening and Enrollment Log** |  |  |
|  | Obtain locator information and record on [site-specific source document] |  |  |
|  | Administer **Behavioral Eligibility Worksheet** |  |  |
|  | Confirm eligibility. Complete and sign off on the **Eligibility Checklist**.   * ELIGIBLE 🡪 CONTINUE   or   * NOT ELIGIBLE 🡪 STOP. Thank and provide reimbursement to participant. Document in **PSF**, **Screening and Enrollment Log** and participant file notes. |  |  |
|  | Verify eligibility and sign off on **Eligibility Checklist** (must be different staff member than above) |  |  |
|  | * Administer **Demographic Information Form (DEM)** * Administer Male or Female **Behavioral Assessment (BA)**, as appropriate *(Note: Not required for Grandmother and Key Informant participants)* |  |  |
|  | Conduct IDI using the **Key Informant In-Depth Interview (IDI) Topic Guide** or applicable **Focus Group Discussion (FGD) Topic Guide**, if necessary |  |  |
| **Post-IDI** | | | |
|  | Thank and reimburse the participant. Provide any other study informational materials, site contact information, and instructions to contact the site for additional information (as needed): *[add site-specific list if desired]* |  |  |
|  | Request permission to contact and document on [site specific log] |  |  |
|  | Complete PSF and other CRFs, as needed |  |  |
|  | Check audio recording to verify that the session was properly recorded |  |  |
|  | Ensure that audio file has been successfully downloaded, saved onto hard drive and CD, and that CD is filed in the participant file. |  |  |
|  | Expand notes and complete **IDI Debriefing Report** |  |  |
|  | Perform QC1 review:  CRFs   * Behavioral Assessment (BA) – *P/BF Women and Male Partners only* * Demographic Information Form (DEM) * Participant Status Form (PSF) * Protocol Deviation Report (PD)\* * Social Harms Report (SH)\*   \*only if necessary  Other Forms   * Behavioral Eligibility Worksheet * Eligibility Checklist * Enrollment Informed Consent Comprehension Checklist * IDI Debriefing Report * Informed Consent Coversheet * Screening and Enrollment Log |  |  |