**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 completed, 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:** |
| --- | --- | --- |
| **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 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 FGD 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**. Make certified copies of any health documentation as needed/available (P/BF women only).* 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 Form (BA), as appropriate

*(Note: Not required for Grandmother FGD participants)* |  |  |
|  | Inform the participant that s/he will now join the FGD with other participants in the same cohort |  |  |
| **Post-FGD**  |
|  | Complete **PSF** and other CRFs, as needed |  |  |
|  | Thank and reimburse participant. Provide any other study informational materials, site contact information, and instructions to contact the site for additional information (as needed): *[add site-specific details]* |  |  |
|  | Request permission to contact and document on [site specific log]  |  |  |
|  | 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 necessaryOther Forms* Behavioral Eligibility Worksheet
* Eligibility Checklist
* Enrollment Informed Consent Comprehension Checklist
* Informed Consent Coversheet
* Screening and Enrollment Log
 |  |  |