**Instructions:** Complete staff initials next to items completed. 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:* Complete visit reminders as outlined in site accrual SOPs
* Confirm tablets are charged and have current data collection materials ready for use
	+ Video
	+ Qualtrics survey (DCE & BDQ)
* Gather supplies: paper & pen for visit notes, consent forms/coversheets/comprehension checklists, placebo products, CRFs (Participant Status Form, Couples Observation Tool, Ideal Product Activity, Protocol Deviation, Social Harms) refreshments (if applicable), reimbursement *(See also SSP section 3.5.2 for details on visit prep)*
* Confirm availability of interview rooms for individual and joint components
 |  |  |
| **Participant Arrival, IC and Data Collection** |
|  | Explain procedures to be performed at visit |  |  |
| **Refer to Individual Checklist items 1-5** |
|  | Verify eligibility of couple.* BOTH PARTNERS ELIGIBLE 🡪 CONTINUE
* EITHER ONE OR BOTH PARTNER(S) NOT ELIGIBLE 🡪 STOP. Thank and provide reimbursement to participant(s). Document in **PSF**, **Screening and Enrollment Log** and participant file notes.
 |  |  |
|  | If both members of the couple eligible, IoR/designee signs **Eligibility Confirmation Form**  |  |  |
| **Refer to Individual Checklist items 6-10** |
|  | Ensure both members of couple have completed the Individual DCE and BDQ before having them rejoin:* Female partner checklist complete
* Male partner checklist complete
 |  |  |
| **Couple comes back together** |
|  | Introduce **Joint DCE** and role of observer |  |  |
|  | Complete **Joint DCE** |  |  |
|  | Administer the **Ideal Product Activity** |  |  |
|  | Observer completes **Couples Observation Tool** |  |  |
|  | **IDI selection*** Determine if couple should be invited
* If eligible, invite
* If accepted, determine if same day or different day
* If same day: conduct IDI-> **Use IDI checklist**
* If different day, schedule separate visit
 |  |  |
|  | Thank and reimburse the participants. 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 (PD, SH), as needed |  |  |
|  | Couples Observation Tool: Expand notes if needed and review CRF for completeness |  |  |
|  | Perform QC review:CRFs* Qualtrics: PTIDs of completed forms
* Couples Observation Tool
* Ideal Product Activity (IPA)
* Participant Status Form (PSF)
* Protocol Deviation Report (PD)\*
* Social Harms Report (SH)\*

\*only if necessaryOther Forms* Eligibility Checklists (Male and Female)
* Eligibility Confirmation Form
* Informed Consent Coversheet
* Enrollment Informed Consent Comprehension Checklist and ICF
* Screening and Enrollment Log
* Both Individual Visit Checklists
* IDI Visit Checklist (if relevant)
* IDI Debriefing Report (if relevant)
 |  |  |