**Instructions:** Complete staff initials next to procedures 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 procedure, e.g., “done by {name}” or “done by nurse.” If a procedure 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.

| **1-Week (Visit 3.0) and 13-Week (7.0) Phone Call Visit Checklist** | | | |
| --- | --- | --- | --- |
| **Procedure** | | **Staff Initials** | **Comments:** |
| 1 | Confirm identity and PTID. |  |  |
| 2 | Review elements of informed consent as needed. Explain procedures to be performed at today’s visit. |  |  |
| 3 | Collect follow-up medical/ medications history: review/update Follow-up Medical History Log and Concomitant Medications Log CRFs as needed. |  |  |
| 4 | Document any adverse events: Complete/update AE Log CRF(s) as needed. If indicated, schedule interim visit for follow-up of identified AEs. |  |  |
| 5 | Provide instructions to report symptoms and/or request information or counseling. |  |  |
| 6 | Provide reimbursement. |  |  |
| 7 | Remind participant of next visit, if applicable. |  |  |
| 8 | Perform QC and DataFax forms to SCHARP DataFax.  **1-Week Phone Call:**   * Follow-up Visit Summary   **13-Week Phone Call:**   * Follow-up Visit Summary * End of Study Inventory * Termination   **For Both Phone Calls:**  **Log CRFs (if newly-completed or updated):**   * Adverse Experience Log * Concomitant Medications Log * Product Hold/Discontinuation Log * Protocol Deviation Log * Missed Visit |  |  |