| **PTID:** | | **Call**  **Date:** |
| --- | --- | --- |
| **\_\_\_\_ Call following Visit 16** | | **\_\_\_\_ Call following Visit 32 (Visit Code 33.0)**  **Note: Visit 33.0 is considered Study Termination Visit** |
|  |  | |
| **Initials** | **Procedures** | |
|  | 1. Confirm participant identity and PTID per site SOPs | |
|  | 2. Review/Update locator information | |
|  | 3. Collect AEs if indicated and document on AE Log form | |
|  | 4. 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 per site SOP. | |
|  | 7. Remind participant of next visit, if applicable. | |
|  | 8. If applicable, fax all completed DataFax forms to SCHARP DataFax:   * Visit Summary (if new AE(s) or Product Holds are reported/initiated) * Adverse Experience Log * Clinical Product Hold/Discontinuation Log * Concomitant Medications Log   **At Visit 33.0 (Study Termination Visit),** complete and fax the following forms to SCHARP DataFax:   * Follow-up Visit Summary * End of Study Inventory * Termination   If applicable at Visit 33.0, fax all completed DataFax forms to SCHARP DataFax:   * Adverse Experience Log * Update Clinical Product Hold/Discontinuation Log * Concomitant Medications * Missed Visit | |