**Instructions:** Complete staff initials next to procedures completed. 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. If any procedures are not conducted on the date recorded above, ensure the date procedure conducted is included in the comments section.

| **Procedure** | | **Staff Initials** | **Comments:** |
| --- | --- | --- | --- |
|  | Confirm that infant has been enrolled (i.e. has attended an in-clinic visit, had informed consent completed, and PTID assigned).   * Infant has been enrolled 🡪 CONTINUE * Infant has **not** been enrolled 🡪 STOP. Discontinue all infant visit procedures for this phone contact. Document in chart notes that infant is not enrolled and procedures cannot proceed. |  |  |
|  | Review elements of informed consent, as needed. Explain procedures for the infant to be performed at today’s visit. |  |  |
|  | Review/update locator information for infant using site-specific form. |  |  |
|  | Provide available test results from previous visit. |  |  |
|  | Complete the **Follow-Up Visit Y/N CRF and the Infant Follow-up Visit Summary CRF** in the infant casebook |  |  |
|  | Review infant health, anthropometry, and feeding history; review infant medications, and collect infant AEs. Complete or update the following CRFs as needed:   * **Pregnancy Outcome CRF** *(mother casebook).* * **Adverse Event Summary/ Log** and **Concomitant Medications Log CRFs (**infant casebook), as needed. |  |  |
|  | Schedule in clinic visit for treatment and/or provision of referrals for care, as required. |  |  |
|  | Perform QC1: while participant is still present (on the phone or at the clinic), review the following for completion and clear documentation:   * **Pregnancy Outcome CRF** * **Follow-up Visit Y/N, Infant Follow-up Visit Summary** * **AE Log(s)** and **Concomitant Medications Log CRFs** to ensure all conditions, medications, AEs are captured consistently and updated. * **Chart notes** |  |  |
|  | Schedule next visit |  |  |
|  | Provide reimbursement |  |  |
|  | Perform QC2 review and ensure that data is entered in Medidata for the following CRFs/forms:  Required CRFs   * Follow-up Visit Y/N * Infant Follow-up Visit Summary   *As needed:*   * Adverse Events Summary/ Log Concomitant Medications Summary/ Log * Pregnancy Outcome CRF |  |  |