**Form to be completed at the time of AE resolution.**

**Adverse Event**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 1 | Today’s Date | |\_\_\_||\_\_\_| / |\_\_\_||\_\_\_| / |\_\_\_||\_\_\_|  *D D M M Y Y* | | | |
| 2 | Form completed for | 1 = Mother 2 = Infant | | | |\_\_\_\_\_| |
| 3 | Did the event result in any of the following:   * Death * Life-threatening event * Hospitalization or prolongation of existing hospitalization * Significant disability or incapacity | | | 1 = Yes 2 = No | |\_\_\_\_\_| |
| **If the answer to question 3 is Yes, then STOP.**  **The event is a Serious Adverse Event (SAE).**  **Follow the SAE reporting instructions in the Manual of Procedures.** | | | | | |
| 4 | The event occurred within 48 hours of which study procedure? | | 1 = Phlebotomy  2 = Vaccination  3 = L/M administration  4 = None of the above | | |\_\_\_\_\_| |
| If the answer to question 4 is ‘None of the above’, then STOP.  The event will not be captured as an Adverse Event. | | | | | |
| 5 | Complete the attached Adverse Event Table to record date(s) of onset and resolution, type(s), and assessment of Adverse Event(s) | | | | |

**NOT DATA ENTERED**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Adverse Event Log completed? (circle response) | | Yes No | |
|  | Interviewer Name and Code | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |\_\_\_||\_\_\_||\_\_\_| |

**Continue to next page and complete the Adverse Event Table.**

**The table will be data entered.**

**Instructions: For each adverse event reported, record the date of onset; enter a code for grading in each category; and record the date of resolution. Every AE should have one code in each of the four categories: severity, relationship, action, and outcome.**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **AE** | **a. Date of Onset** | **b. Severity\*** | | | **c. Relationship\*\*** | | | **d. Action** | | | | | **e. Outcome** | | | | **f. Date of Resolution** |
|  | **DD/MM/YY** | **1.**  **Mild** | **2. Mod** | **3. Severe** | **1.**  **Definite** | **2.**  **Possibly** | **3.**  **Unrela-ted** | **1. None** | **2. Remedial**  **therapy** | **3. Discontinuation** | **4. Hospitalization^^** | **5. Other** | **1. Resolved** | **2.**  **Continuing** | **3. Death**  **^^** | **4. Unknown /**  **lost to F/U** | **DD/MM/YY** |
| **5A. Post-Phlebotomy** | | | | | | | | | | | | | | | | | |
| 1. Infection |  |  | | |  | | |  | | | | |  | | | |  |
| 2. Fever |  |  | | |  | | |  | | | | |  | | | |  |
| 3. Bleeding |  |  | | |  | | |  | | | | |  | | | |  |
| 4. Bruising |  |  | | |  | | |  | | | | |  | | | |  |
| 5. Swelling |  |  | | |  | | |  | | | | |  | | | |  |
| 6. Irritability |  |  | | |  | | |  | | | | |  | | | |  |
| **5B. Post-Vaccination** | | | | | | | | | | | | | | | | | |
| 1. Fever |  |  | | |  | | |  | | | | |  | | | |  |
| 2. Swelling |  |  | | |  | | |  | | | | |  | | | |  |
| 3. Redness |  |  | | |  | | |  | | | | |  | | | |  |
| 4. Vomiting |  |  | | |  | | |  | | | | |  | | | |  |
| 5. Diarrhea |  |  | | |  | | |  | | | | |  | | | |  |
| 6. Broncho-spasm |  |  | | |  | | |  | | | | |  | | | |  |
| 7. Otitis Media |  |  | | |  | | |  | | | | |  | | | |  |
| 8. Naso-pharyngitis |  |  | | |  | | |  | | | | |  | | | |  |
| 9. Other |  |  | | |  | | |  | | | | |  | | | |  |
| **5C. Post-L/M Solution** | | | | | | | | | | | | | | | | | |
| 1. Vomiting |  |  | | |  | | |  | | | | |  | | | |  |
| 2. Loose stools |  |  | | |  | | |  | | | | |  | | | |  |

\*See the Manual of Procedures for Severity Grading Tables with definitions of mild, moderate, and severe.

**\*\***See study protocol for definitions of definitely related, possibly related, and unrelated.

**^^** If subject was hospitalized for this event or death occurs, the event is a Serious Adverse Event. Follow the SAE reporting instructions in the Manual of Procedures.