**Adverse Event Tracking Log**

**Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ IRB #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Sponsor: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Study Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **#** | **Subject****ID** | **Date of Event** | **Date PI Aware** | **Description of Event** | **Serious** | **Expected** | **Related to Study Drug** | **Reported to IRB\*** | **Reported to Sponsor\***  | **Reported to FDA\*** |
| **Yes** | **No** | **Yes** | **No** | **Yes** | **No** | **Unk** |
| **1** |  |  |  |  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |  |  |  |
| **2** |  |  |  |  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |  |  |  |
| **3** |  |  |  |  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |  |  |  |
| **4** |  |  |  |  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |  |  |  |
| **5** |  |  |  |  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |  |  |  |
| **6** |  |  |  |  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |  |  |  |
| **7** |  |  |  |  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |  |  |  |
| **8** |  |  |  |  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |  |  |  |
| **9** |  |  |  |  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |  |  |  |
| **10** |  |  |  |  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |  |  |  |
| **11** |  |  |  |  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |  |  |  |
| **12** |  |  |  |  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |  |  |  |

**\* *If applicable***