**PROTOCOL DEVIATION TRACKING LOG**

Principal Investigator:

Protocol #:

### Study Title:

### Sponsor:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Subject** | **Date of Violation or Deviation** |  **Description and Corrective Action** | ***IRB & Sponsor Approval Prior to Deviation?*** | ***Date IRB Notified*** | ***Date Sponsor Notified*** |
| **1** |  |  |  | [ ]  Yes [ ]  No |  |  |
| **2** |  |  |  | [ ]  Yes [ ]  No |  |  |
| **3** |  |  |  | [ ]  Yes [ ]  No |  |  |
| **4** |  |  |  | [ ]  Yes [ ]  No |  |  |
| **5** |  |  |  | [ ]  Yes [ ]  No |  |  |
| **6** |  |  |  | [ ]  Yes [ ]  No |  |  |
| **7** |  |  |  | [ ]  Yes [ ]  No |  |  |
| **8** |  |  |  | [ ]  Yes [ ]  No |  |  |
| **9** |  |  |  | [ ]  Yes [ ]  No |  |  |
| **10** |  |  |  | [ ]  Yes [ ]  No |  |  |

 \* Report all violations/deviations/exceptions in accordance with IRB and sponsor requirements