**SUBJECT DEVIATION TRACKING LOG**

Principal Investigator:

Protocol #:

Subject #:

### Study Title:

### Sponsor:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Date of Violation or Deviation** | **Date of Violation/ Deviation Identified** | **Description and Corrective Action** | ***IRB & Sponsor Approval Prior to Deviation?*** | ***Date Sponsor Notified*** | ***IRB Reportable*** | ***Date IRB Notified* (*if reportable*)** | ***PI Initial/Date*** |
| **1** |  |  |  | Yes  No |  | Yes  No |  |  |
| **2** |  |  |  | Yes  No |  | Yes  No |  |  |
| **3** |  |  |  | Yes  No |  | Yes  No |  |  |
| **4** |  |  |  | Yes  No |  | Yes  No |  |  |
| **5** |  |  |  | Yes  No |  | Yes  No |  |  |
| **6** |  |  |  | Yes  No |  | Yes  No |  |  |
| **7** |  |  |  | Yes  No |  | Yes  No |  |  |
| **8** |  |  |  | Yes  No |  | Yes  No |  |  |
| **9** |  |  |  | Yes  No |  | Yes  No |  |  |
| **10** |  |  |  | Yes  No |  | Yes  No |  |  |

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