|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Subject ID** | **Date of Deviation** | **Date Identified** | **Deviation Description** | **Deviation Code a** | **Report to IRB?**  **Yes/No (circle)**  **\*\*If Yes to 1 OR 2 OR 3 COMPLETE**  **AND**  **file Report Form to IRB w/in 5 days of awareness of event** | **Corrective**  **Action**  **Plan** | **PI Initial** | **PI**  **Date** |
|  |  |  |  |  | Yes, date:\_\_\_\_\_\_\_ No |  |  |  |
|  |  |  |  |  | Yes, date:\_\_\_\_\_\_\_ No |  |  |  |
|  |  |  |  |  | Yes, date:\_\_\_\_\_\_\_ No |  |  |  |
|  |  |  |  |  | Yes, date:\_\_\_\_\_\_\_ No |  |  |  |
|  |  |  |  |  | Yes, date:\_\_\_\_\_\_\_ No |  |  |  |
|  |  |  |  |  | Yes, date:\_\_\_\_\_\_\_ No |  |  |  |

**aDeviation Codes: A** - Consent Procedures **B** - Inclusion/Exclusion Criteria **C** - Con Med/Therapy **D** - Lab Assessments/Procedures **E** - Study Procedures **F** -SAE Reporting/Unanticipated Problem

**G**- Randomization **H** -Visit Schedule/Interval **I** -Efficacy Ratings **J**-Procedures/Study Drug Dosing **K**-Other- specify

**IRB Reporting Requirements: \*\*If Yes to 1 OR 2 OR 3 COMPLETE PROTOCOL DEVIATION REPORT AND Report Form to IRB**

**1**. Intended to eliminate apparent immediate hazard to a research participant (such as changing the dose of a medication due to possible toxicity), **or**

**2**. Harmful, caused possible harm to participants or others, or places them at increased risk of harm includes physical, psychological, economic, or social harm, such as a breach of confidentiality), **or**

**3**. Possible serious or continued noncompliance (such as a deviation that has happened previously and is now being repeated).

(At close out of study) **PI Signature**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_