# Protocol Deviation Tracking Log

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Protocol ID/Number:** | | |  | | **Site Name:** | |  | | |
| **Protocol Title:** | | |  | |
| **Principal Investigator:** | | |  | | **Page number [1]:** | |  | | |
| **Ref No.** | **Subject ID** | **Date of Deviation** | **Date Identified** | **Deviation Description** | **Dev. Type [2]** | **Resulted in AE?** | **Did Subject Continue in Study?** | **Meets IRB Reporting Req. (Yes/No)** | **IRB Reporting Date** |
| **1** |  |  |  |  |  |  |  |  |  |
| **2** |  |  |  |  |  |  |  |  |  |
| **3** |  |  |  |  |  |  |  |  |  |
| **4** |  |  |  |  |  |  |  |  |  |
| **5** |  |  |  |  |  |  |  |  |  |
| **6** |  |  |  |  |  |  |  |  |  |
| **7** |  |  |  |  |  |  |  |  |  |

**Investigator Signature:** **Date:**

## Form Instructions:

Protocol Deviation Codes:

A – Consent Procedures

B – Inclusion/Exclusion Criteria

C – Concomitant Medication/Therapy

D – Laboratory Assessments/Procedures

E – Study Procedures

F – Serious Adverse Event Reporting/Unanticipated Adverse Device Effect

G – Randomization Procedures/Study Drug Dosing

H – Visit Schedule/Interval

I – Efficacy Ratings

J – Other