**Deviation Tracking Log**

**Instructions**

1. Use this form to track deviations that occur during a research project and to present a summary of events for the Continuing Review process.
2. Major deviations are required to be reported to the WVU ORB within ten days of the event.
3. Minor deviations are reporting during the Continuing Review process.

**Guidance**

1. Review the following information on the WVU Office of Human Research Protections website:
* Research Related Event Reporting Definitions
* Research Related Event Reporting Requirements
* Research Related Event Reporting Process Flow

**Principal Investigator:**

**IRB Protocol Number:**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Ref No.** | **Subject ID** | **Date of Onset** | **Date Identified** | **Deviation Description** | **Type** | **PI Determination** | **Reported to Sponsor** | **IRB Reporting Requirements** | **Date Reported to IRB** | **Date Acknowledged by IRB** |
| **1** |  |  |  |  | [ ]  In[ ]  F/Up | [ ]  Unexpected[ ]  Related[ ]   [Serious](https://www.fda.gov/Safety/MedWatch/HowToReport/ucm053087.htm) | [ ]  Yes[ ]  NoDate: \_\_\_\_\_\_ | [ ]  5 days [ ]  Time of CR  |  |  |
| **2** |  |  |  |  | [ ]  In[ ]  F/Up | [ ]  Unexpected[ ]  Related[ ]  [Serious](https://www.fda.gov/Safety/MedWatch/HowToReport/ucm053087.htm) | [ ]  Yes[ ]  NoDate: \_\_\_\_\_\_ | [ ]  5 days [ ]  Time of CR |   |  |
| **3** |  |  |  |  | [ ]  In[ ]  F/Up | [ ]  Unexpected[ ]  Related[ ]  [Serious](https://www.fda.gov/Safety/MedWatch/HowToReport/ucm053087.htm) | [ ]  Yes[ ]  NoDate: \_\_\_\_\_\_ | [ ]  5 days [ ]  Time of CR  |   |  |
| **4** |  |  |  |  | [ ]  In[ ]  F/Up | [ ]  Unexpected[ ]  Related[ ]  [Serious](https://www.fda.gov/Safety/MedWatch/HowToReport/ucm053087.htm) | [ ]  Yes[ ]  NoDate: \_\_\_\_\_\_ | [ ]  5 days [ ]  Time of CR  |   |  |
| **5** |  |  |  |  | [ ]  In[ ]  F/Up | [ ]  Unexpected[ ]  Related[ ]  [Serious](https://www.fda.gov/Safety/MedWatch/HowToReport/ucm053087.htm) | [ ]  Yes[ ]  NoDate: \_\_\_\_\_\_ | [ ]  5 days[ ]  Time of CR  |   |  |
| **6** |  |  |  |  | [ ]  In[ ]  F/Up | [ ]  Unexpected[ ]  Related[ ]  [Serious](https://www.fda.gov/Safety/MedWatch/HowToReport/ucm053087.htm) | [ ]  Yes[ ]  NoDate: \_\_\_\_\_\_ | [ ]  5 days[ ]  Time of CR  |   |  |
| **7** |  |  |  |  | [ ]  In[ ]  F/Up | [ ]  Unexpected[ ]  Related[ ]  [Serious](https://www.fda.gov/Safety/MedWatch/HowToReport/ucm053087.htm) | [ ]  Yes[ ]  NoDate: \_\_\_\_\_\_ | [ ]  5 days[ ]  Time of CR  |   |  |
| **8** |  |  |  |  | [ ]  In[ ]  F/Up | [ ]  Unexpected[ ]  Related[ ]  [Serious](https://www.fda.gov/Safety/MedWatch/HowToReport/ucm053087.htm) | [ ]  Yes[ ]  NoDate: \_\_\_\_\_\_ | [ ]  5 days[ ]  Time of CR  |  |  |

Principal Investigator Signature: Date: Click or tap to enter a date.