|  |  |  |  |
| --- | --- | --- | --- |
| **Principal Investigator:** |  | **IRB Protocol Number:** |  |
| **Ref No.** | **Subject ID** | **Date of Onset** | **Date Identified** | **SAE 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  |  |  |

**Note: All events that meet with all three criteria must be reported to the WVU IRB within five working days of occurrence or within five working days of the Investigator becoming aware of the occurrence. A summary of all research related events are reported at the time of continuing review.**

**Investigator Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**