



**PROTOCOL DEVIATION and/or PROTOCOL VIOLATION SUBMISSION**

**DEFINITIONS**

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| Protocol Deviation | An inadvertent act (from the perspective of the PI and study staff) in which the protocol is not followed.<br><i>Examples include: accidental misread of a laboratory value/test result, accidental discarding of tissue/samples required for study.</i> |
| Protocol Violation | An intentional act (from the perspective of the PI and study staff) in which the protocol is not followed.<br><i>Examples include: subject being given wrong study drug/device, intervention follow up visits scheduled outside of window.</i>           |

**SECTION 1: GENERAL STUDY INFORMATION**

|                                       |                                    |
|---------------------------------------|------------------------------------|
| H.S.#:                                |                                    |
| Study Title:                          |                                    |
| Principal Investigator:               | Study Coordinator:                 |
| Current Protocol Version Number/Date: | Current Consent Form Version Date: |

**SECTION 2: REPORTABLE EVENT INFORMATION**

|   |   |
|---|---|
| Event Identification Number:  |   |
| Did this event occur within: (check all that apply)<br><input type="checkbox"/> the enrollment process (inclusion/exclusion criteria, recruitment, etc.)<br><input type="checkbox"/> the consenting process<br><input type="checkbox"/> the drug and/or device administration (dosage, schedule, route of administration, formulation, etc.)<br><input type="checkbox"/> any other protocol activities (data analysis, reporting, etc.) |   |
| Event Detail Description:   |   |
| This report is:   | <input type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOW-UP # |
| Have similar events been reported previously?<br>If yes, how many times have similar events occurred to date?   | <input type="checkbox"/> Yes <input type="checkbox"/> No              |
| Date event occurred:  | Date event ended:   |
| Did this event adversely affect: (check all that apply)<br><input type="checkbox"/> the rights and/or welfare of the subject<br><input type="checkbox"/> the safety of the research subject<br><input type="checkbox"/> the integrity of the research data<br><input type="checkbox"/> the subject's willingness to continue participation in the study   |   |
| Detail how and/or why this event occurred:  |   |
| Detail corrective actions taken to alleviate this deviation/violation:  |   |
| Detail correction actions taken to ensure similar deviations/violations do not occur:   |   |

*Add all events to the Protocol Deviation and Protocol Violation Tracking Log. Submit the revised log with each event submission.*

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| I submit the above information to the CAMC/WVU-Charleston Division IRB. |       |
| Principal Investigator's Signature                                      | Date: |