



## **PROTOCOL DEVIATION/VIOLATION REPORTING PROCEDURES**

*Effective September 1, 2009*

### **DEFINITIONS**

**PROTOCOL DEVIATION** is an inadvertent act (from the perspective of the PI and study staff) in which the protocol is not followed. *Examples include: accidental misread of a laboratory value/test result, accidental discarding of tissue/samples required for study.*

**PROTOCOL VIOLATION** is an intentional act (from the perspective of the PI and study staff) in which the protocol is not followed. *Examples include: subject being given wrong study drug/device, intervention follow up visits scheduled or conducted outside of window.*

### **DESCRIPTION**

Submissions of Protocol Deviations and Protocol Violations must be submitted to the Research and Grants Administration Office when the event is likely to adversely affect: 1) the rights and welfare of the research subject; 2) the safety of the research subject; 3) the integrity of the research data; and/or 4) the subject's willingness to continue participation in the study.

### **RESPONSIBILITY**

The Principal Investigator is responsible to ensure all reportable Protocol Deviations and Protocol Violations are submitted to the IRB through the Research and Grants Administration Office within the required time frame.

### **REPORTING PROCESS**

Protocol Deviations and Protocol Violations as described above must be submitted to the CAMC/WVU-Charleston Division IRB within 10 (ten) business days of the time the Principal Investigator and/or study staff become aware of the event. However, a protocol deviation or protocol violation that has resulted or potentially resulted in a death must be reported to the CAMC/WVU-Charleston Division IRB within 24 (twenty-four) hours of the occurrence of the event.

All Protocol Deviations and Protocol Violations must be submitted using the Protocol Deviation/Violation Reporting Form.

In addition to the Protocol Deviation/Violation Reporting Form a Protocol Deviation and Protocol Violation Reporting Log must be submitted. The Protocol Deviation and Protocol Violation Reporting Log must be comprehensive including all deviations and violations that have occurred from the onset of the trial.

All paperwork must be submitted to the Research and Grants Administration Office per the Submissions Procedure.

### **REVIEW PROCESS**

The Research and Grants Administration Office staff will conduct an initial review of all submitted Protocol Deviations and Protocol Violations. Submitted Protocol Deviations and Protocol Violations that are determined to be repetitive, have resulted in the death or serious harm to the subject will be placed on the agenda of the next scheduled meeting of the CAMC/WVU-Charleston Division IRB.