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**Protocol Deviation or Noncompliance – Self-Report**

**The CGU IRB requires that investigators/sites report violations that affect the safety and welfare of the subject to be submitted within 48 hours from the moment the Investigator becomes aware of the event.**

* Minor Deviations that do not affect the safety and welfare of the subject may be submitted at the time of continuing review. Please note that the sponsor’s requirement may differ from the CGU IRB’s reporting requirements; contact the sponsor to confirm if you have any questions regarding their policy.
* Planned protocol deviations require prior approval of the IRB except when necessary to eliminate apparent immediate hazards to human subjects.

Report Date:

CGU IRB Protocol #

Protocol Title:

Principal Investigator Name:

For Student Investigators, list your Faculty Advisor:

Department/Division:

Sponsored/Funder, if applicable:

Date of Deviation (earliest, if more than one):

Did the protocol deviation/violation affect the safety and welfare of the subject(s)? [ ]  Yes [ ]  No

Will the subject continue his/her participation in the study? [ ]  Yes [ ]  No

Was the deviation planned? [ ]  Yes [ ]  No

Deviation Description and Reason:

Proposed Corrective Action: