Subject: Reporting Noncompliance with the Protocol

Definitions:
1. Data and Safety Monitoring: A plan to oversee the implementation of a study protocol for compliance monitoring.
2. Noncompliance: An incident involving non-adherence to the protocol. Noncompliance may result from the action of the participant, Investigator, or staff. Noncompliance does not occur as a deliberate, purposeful change to an approved protocol. It is an unplanned and unintended change to the protocol whereas an amendment is an intentional and planned change. NOTE: This definition may not match the PI or Sponsor’s definition.
3. Adverse Event: An untoward or undesirable experience or any undesirable experience associated with the use of a medical product in a patient.
4. Serious: An event is “serious” if it involved a serious harm to one or more persons (who may or may not be participants), or required intervention to prevent one or more persons from experiencing serious harm.
5. Unanticipated: An event is “unanticipated” when it was unforeseeable at the time its occurrence. The word unanticipated, is not a synonym for unexpected. A research protocol can monitor for an unexpected event, but cannot monitor for an unforeseen event. All unanticipated events are unexpected, but not vice versa.
6. Unanticipated Problems Involving Risk to Participants or Others: Any event that was (1) unanticipated, (2) serious, and (3) related.
7. Related: An event is “related” if it is likely to have been caused by the research procedures.

Policy:
It is the policy of the HRPP to be notified of any noncompliance with the protocol that result in an increase in risk or a decrease in potential benefit to participants.

I. Noncompliance.
1. It is the responsibility of the Investigator not to deviate from the protocol approved by the IRB, except to avoid an immediate hazard to the participant. The Investigator must submit an amendment request to the IRB and receive written approval prior to implementation of any change to the protocol.
2. When a sponsor requests that the IRB be notified of noncompliance, the IRB will perform an expedited review of the “Notification of Noncompliance with the Protocol” submitted by the Investigator.
3. Repetitive noncompliance may be ruled by the IRB to constitute serious or continuing noncompliance.

II. Instances where a change to the protocol has occurred to avoid immediate apparent hazard to a participant may be reported as noncompliance with the protocol.

References:
21 CFR 56.108
HRPP Policy III.J