IV. Policy

Protocol deviations associated with an IRB approved protocol must be reported to the Research Integrity office for a compliance assessment and, if necessary, review by the IRB.

V. Definitions

Protocol Deviation: Any exception or change to a research protocol that is not approved by the IRB prior to its initiation or implementation.

*A protocol deviation may be categorized as **major** or **minor**.*

A **major deviation** is one that: a) has increased the risk and/or decreased the benefit to individual participants,
clinical or emotional status, or compromised the integrity or validity of the study; b) has occurred without appropriate IRB review and approval; c) is egregious or intentional; and/or d) has been determined by the IRB to be a major deviation.

A **minor deviation** is an unintentional deviation or omission from a protocol that does not impact research participant safety or does not substantially alter risks to research participants.

Continuing Non Compliance:
involves repeated incidents which suggest that noncompliance will continue unless the IRB intervenes. For example, the IRB may determine that repeated minor deviations (continuing non-compliance) are equivalent in severity to a major deviation.

VI.

The Research Integrity office will be responsible for:

Receiving and assessing protocol deviation reports

Communicating the and required corrective actions (if any) to the investigator in writing.

Following up with the investigator to ensure and document that the corrective action has been taken.

Reporting major protocol deviations to the appropriate institutional officials