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INSTITUTIONAL ETHICS REVIEW COMMITTEE

GaU-ISERC DEVIATION REPORTING FORM

GaU-ISERC NO.: _____

Title of Project _____

Note:

- (a) Deviation: When without significance consequences the research activities diverge from the approved protocols procedures (emergency or non-emergency)
- (b) Violation: A divergence from the approved protocol that materially reduces the quality or completeness of the data or makes the informed consent form inaccurate or impact on subjects safety rights or welfare (journal of clinical research, 2005).

- 1. Date of occurrence of the event _____
- 2. Nature of deviation or Violation (please explain)

- 3. Any action taken (yes or no) If yes explain

- 4. What measures can be taken to preclude future recurrence of deviation or violation

- 5. Has the project sponsor (if any) been notified? _____

Name and signature of Principal Investigator

Date

Name and signature of the receiving officer

Date