

**DECATUR MEMORIAL HOSPITAL  
INSTITUTIONAL REVIEW BOARD**

**SUBJECT:** PROTOCOL DEVIATION/VIOLATION MONITORING

**STANDARD:** PATIENT RIGHTS AND ORGANIZATION ETHICS

**EFFECTIVE:** 11/03

**POLICY:** The IRB shall review all protocol deviations/violations to assure the rights and welfare of humans participating as subjects in research are protected. Improvements to work processes and re-education/training of staff are often implemented following a deviation or violation. The identification and reporting of deviations impact the conduct and analysis of a clinical trial and the risk to its subjects. Consistent or numerous deviations/violations may necessitate amendments of operational issues or trial closure for subject protections.

**PERFORMED BY:** IRB

**IMPLEMENTATION:**

Deviations/violations may consist of, but are not limited to, the following:

- 1) Altered appointment window
- 2) Errors in dispensing the study agent (wrong dose, wrong subject/patient, wrong agent, wrong method)
- 3) Missed or altered assessments or assessment windows
- 4) Lack of HIPAA Authorization (if HIPAA Authorization is separate) prior to informed consent
- 5) Lack of informed consent prior to study enrollment
- 6) Failure to use the proper IRB approved informed consent form
- 7) Enrollment of a participant that did not meet inclusion/exclusion criteria
- 8) Protocol and informed consent form not approved prior to subject screening/enrollment or study procedures

The investigator/clinical research associate shall notify the IRB upon realization of a protocol deviation/violation.

- 1) The investigator/clinical research associate shall submit a Protocol Deviation/Violation form signed by the principle investigator.
- 2) This form can be immediately acted upon by the IRB Chairperson or held until the next full board meeting.

The IRB Chairperson may:

- 1) Suspend or terminate study approval immediately in order to eliminate immediate hazard to the subjects until the next full board meeting
- 2) Convene an interim meeting of the full board to review the report
- 3) Hold for the next full board meeting

The full board IRB may:

- 1) Approve the report with no changes to the protocol or consent
- 2) Approve the report with required changes to the protocol or consent
- 3) Suspend or terminate the study approval until further notice
- 4) Permanently terminate the study approval

Following the full board IRB meeting, the investigator will be notified in writing within ten days following review of the report of the IRB's decision. If the study is suspended or terminated, the final decision will include reasoning for the decision and give the investigator an opportunity to respond in person or writing (See "Appeal Procedure"). DMH Administration and applicable department or agency heads shall also be notified of the reason for the suspension or termination of a study.

**DOCUMENTATION:** IRB MINUTES; PROTOCOL DEVIATION/VIOLATION FORM

**APPLICABLE TO:** IRB MEMBERS & INVESTIGATORS

**APPROVED BY:**

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President and CEO