

**DECATUR MEMORIAL HOSPITAL
INSTITUTIONAL REVIEW BOARD**

SUBJECT:	RESEARCH MISCONDUCT AND NON-COMPLIANCE	
STANDARD:	PATIENT RIGHTS AND ORGANIZATION ETHICS	EFFECTIVE: 09/05

PURPOSE: Research misconduct non-compliance undermines the promotion of the health and safety of research participants, the integrity of research, and those who strive to ensure the safety of research participants. Decatur Memorial Hospital Institutional Review Board seeks to ensure that all research overseen by said committee is conducted in accordance with 42 CFR 93.

PERFORMED BY: Full IRB Review

PROCEDURE:

The definition of scientific misconduct, and procedures for investigating and reporting allegations of misconduct at Decatur Memorial Hospital concur with those set forth in 42 CFR 93.

According to 42 CFR 93.103 Research Misconduct includes fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research misconduct does not include honest error or differences of opinion.

The IRB shall promptly review all reported instances of research misconduct and non-compliance according to 42 CFR 93 and DMH IRB policies.

Reporting Misconduct or Non-Compliance:

Requirements of Findings of Research Misconduct:

A finding of research misconduct made under this part requires that all of the following must be met:

- 1) There be a significant departure from accepted practices of the relevant research community
- 2) The misconduct be committed intentionally, knowingly, or recklessly
- 3) The allegation be proven by a preponderance of the evidence

The IRB Shall:

- 1) Notify the investigator in writing, within ten days of the meeting date regarding the instance of non-compliance and require compliance. Notification shall include an opportunity for the investigator to respond in writing or in person.
- 2) Require documentation from the investigator that compliance has occurred.

For Serious or Continuing Non-Compliance the IRB may:

- 1) Stop the research. The investigator will be notified in writing, by the IRB Chairperson to:
 - a) Stop all research activities;
 - b) Notify all subjects currently participating in the research that the study has been terminated;
 - c) Follow procedures for withdrawal of enrolled subjects that consider the rights and welfare of the subjects;
 - d) Inform the subjects of any safety related follow-up requirements;
 - e) Submit documentation to the IRB that the above listed criteria has been accomplished as soon as possible, but no later than the next scheduled IRB meeting;
 - f) Report any study related adverse events/outcomes to the IRB.

- 2) Notify the investigator in writing within ten days of the meeting date and provide an opportunity to respond in person or in writing regarding serious or continuing non-compliance.
- 3) Require more frequent (greater than annual) periodic review verification from other sources that no material changes have occurred since previous IRB review.
- 4) Require verification from other sources that no material changes have occurred since previous IRB review
- 5) Require the consent process and research be observed by a member of the IRB or a third party appointed by the IRB Chairperson.

The IRB will promptly notify (in writing), DMH Administration, OPRR and the appropriate DHHS Program Office or its designee, of any serious or continuing non-compliance with the provisions of the DMH Assurance and/or the Federal Policy for the Protection of Human Subjects or determinations of the IRB, any suspension or termination of IRB approval of the research, and any unanticipated injuries or problems involving risks to subjects or others.

DOCUMENTATION:

- 1) Copies of all correspondence between the IRB and the investigators shall be retained for at least three years, and records related to research, which is conducted, shall be retained for at least three years after completion of the research.
- 2) The IRB minutes shall document meeting attendance, actions taken by the IRB, the vote on these actions, including the number of members voting for, against, and abstaining, the basis for the finding of noncompliance, a written summary of the discussion of controverted issues and their resolution, and a statement regarding compliance with prohibition of deliberation and voting by Investigators/IRB members with a conflict of interest (if applicable).

APPLICABLE TO: IRB members, Investigators

APPROVED BY:

President and CEO