

**DECATUR MEMORIAL HOSPITAL
INSTITUTIONAL REVIEW BOARD**

SUBJECT:	INVESTIGATOR NON-COMPLIANCE	
STANDARD:	PATIENT RIGHTS AND ORGANIZATION ETHICS	EFFECTIVE: 1/98

PURPOSE: To assure that all human subject research is conducted in accordance with the Federal Regulations for the Protection of Human Research Subjects, the DMH Assurance, and the IRB requirements and determinations.

PERFORMED BY: Full IRB Review

PROCEDURE:

The IRB shall promptly review all reported instances of Investigator non-compliance with the Federal Regulations regarding research on human subjects, the DMH Assurance, and/or IRB requirements and determinations.

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