

**DECATUR MEMORIAL HOSPITAL
INSTITUTIONAL REVIEW BOARD**

SUBJECT: APPEAL OF IRB DECISION
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STANDARD: PATIENT RIGHTS AND ORGANIZATION ETHICS

EFFECTIVE: 1/98

POLICY: To provide a mechanism for Investigator appeal of decisions made by the IRB.

PERFORMED BY: Full IRB Review

IMPLEMENTATION:

Criteria for appeal:

- 1) Any decision regarding the protocol review, including approval, disapproval, consent form modifications, and additional stipulations placed on the research may be appealed by the investigator.
- 2) The appeal may be done in person or in writing, and must be addressed to the Chairperson of the IRB.

Resolution:

- 1) Override of the IRB disapproval by DMH officials is prohibited. Hospital officials may not approve research if it has not been approved by the IRB.
- 2) The appeal will be resolved through the full IRB review at the request of the Investigator and/or Chairperson.
- 3) When the appeal is brought before the IRB, the Investigator will provide (in person, or in writing) the reason(s) for the appeal. The Investigator must be present at the IRB review of the appeal in order to answer any questions the IRB members may have. The Investigator may not be present for deliberations or voting regarding appeal.

DOCUMENTATION:

- 1) The IRB secretary will notify the Investigator, in writing, of the outcome of the appeal within 10 days of the meeting date.
- 2) It is the Investigator's responsibility to notify the sponsor of the research (if applicable).
- 3) Written documentation of the action taken will be sent to DMH Administration within ten days following the meeting date of the IRB appeals decision. The IRB minutes shall be made available for Administrative review upon request.
- 4) 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 requiring changes in or disapproving the research, 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: Investigators, IRB members

APPROVED BY:

President and CEO