

**DECATUR MEMORIAL HOSPITAL  
INSTITUTIONAL REVIEW BOARD**

<b>SUBJECT:</b> CHANGE IN APPROVED RESEARCH ACTIVITY
<b>STANDARD:</b> PATIENT RIGHTS AND ORGANIZATION ETHICS <b>EFFECTIVE:</b> 1/98

**POLICY:** To assure protection of the rights and welfare of human research subjects, changes in the IRB approved research projects must be reviewed and approved by the IRB prior to implementation, unless the change is necessary to eliminate apparent immediate hazards to the subject.

**PERFORMED BY:**

Expedited Review: IRB Chairperson or one or more experienced reviewers chosen by the Chairperson from among the members of the IRB.  
Full Board Review: IRB Members

**IMPLEMENTATION:**

The Investigator shall be notified upon protocol review of the following requirements: 1) prompt reporting to the IRB of any proposed changes in the research 2) changes in research activity during the period for which IRB approval has already been given may *not* be initiated without IRB review and approval *except* where necessary to eliminate immediate hazard to the subject. In this case, the IRB must be promptly informed--review will occur at the next scheduled IRB meeting. Written notification of the above shall be included in the "Report of Protocol Review" sent to the Investigator.

- 1) Upon notification of a proposed change in the research activity, the Investigator will submit an "Amendment/Revision Summary" form to the IRB. One copy of the summary, amendment, revision and pages of the protocol/informed consent (including the model-informed consent) which are affected must be included.
- 2) The IRB Chairperson, or one or more experienced reviewers chosen by the chairperson from among members of the IRB, will make the determination if the change necessitates full board or expedited review. Only *minor* changes in previously approved research during the period (of one year or less) for which approval is authorized may be expedited. This includes administrative/clerical changes and those changes which do not impact the risk/benefit ratio.
- 3) If the change is not minor and requires full IRB review, the Investigator will be notified of the scheduled review date. Approval of the change in research is contingent upon the criteria set forth in the procedure for initial and continuing protocol review.
- 4) If the change qualifies for expedited review, the IRB Chairperson or one or more experienced reviewers chosen by the Chairperson from among members of the IRB will review the proposed change. Actions that may be taken include:
  - a) approve the protocol/consent form change as submitted;
  - b) approve the protocol/consent for change with revisions. The change may not be disapproved through the expedited review process.

**DOCUMENTATION:**

Full Board and Expedited Review:

- 1) The Investigator will be informed in writing, within 10 days following the review date, of the decision made by the IRB. The IRB secretary via Report of Protocol Review form will notify the Investigator; a 310 form will be generated for CCOP protocols; a letter will be generated for other trials.
- 2) It is the Investigator's responsibility to inform the study sponsor of the results of the IRB review.
- 3) Written documentation of actions taken by the full IRB will be sent to DMH Administration within ten days following the meeting date of the decision. Documentation of expedited review actions taken within the previous month will be included in the report. IRB meeting minutes shall be made available for Administrative review upon request.

Full Board Review Only (4 & 5):

- 4) If disapproved, Investigator notification shall include the reason(s) for the decision and give the investigator an opportunity to respond in person or writing (See "Appeal" procedure).
- 5) 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