

**DECATUR MEMORIAL HOSPITAL
INSTITUTIONAL REVIEW BOARD**

SUBJECT: CONTINUING REVIEW OF APPROVED RESEARCH

STANDARD: PATIENT RIGHTS AND ORGANIZATION ETHICS **EFFECTIVE:** 1/98; 05/09

POLICY:

Continuing review of approved research must be substantive and meaningful. HHS regulations at 45 CFR 46.111 set forth the criteria that must be satisfied in order for the IRB to approve research. These criteria include, among other things, determinations by the IRB regarding risks, potential benefits, informed consent, and safeguards for human research participants.

Specific Policies

Criteria for Conducting Continuing Review

Since the purpose of the continuing review is to review the progress of the entire study and not just changes in it, the DMH IRB will revisit the same criteria used to grant the initial approval. It will also consider whether any new information or unanticipated harms have emerged either from the research itself or from other sources since the previous IRB review.

Review Process

Continuing review of a study may not be conducted through an expedited review procedure, unless (1) the study was eligible for, and initially reviewed by, an expedited review procedure, or (2) the study has changed such that the only activities remaining are eligible for expedited review.

Interval for Continuing Review

The DMH IRB will conduct continuing reviews of all research at intervals appropriate to the degree of risk, but not less frequently than once per year.

Lapse in IRB Approval

The regulations make no provision for any grace period extending the conduct of research beyond the expiration date of IRB approval. Therefore, continuing review and re-approval of research must occur on or before the date when IRB approval expires.

If the IRB has not reviewed and approved a research project by the study's current expiration date, i.e. IRB approval has expired, all research activity must stop. No new patients may be enrolled in the study. However, if the investigator is actively pursuing renewal with the IRB and the IRB believes that an overriding safety concern or ethical concern exists, then the IRB may permit the study to continue for the brief time required to complete the review process.

APPLICABLE TO:

These policies and procedures apply to the research conducted at Decatur Memorial Hospital.

RESPONSIBILITY:

The IRB Administrator is responsible for ensuring that IRB reviewers have all the tools and resources they need to complete their research reviews.

APPROVED BY:

President and CEO