

**DECATUR MEMORIAL HOSPITAL
INSTITUTIONAL REVIEW BOARD**

SUBJECT: CATEGORIES OF ACTION

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

POLICY:

As a result of its review, the IRB may decide to approve or disapprove the proposed research activity, or it may make some modification to secure IRB approval of the research activity. Except when the expedited review procedure is used, these actions will be taken by a vote of a majority of the regular and alternate members present, except for those members present but unable to vote in accordance with the IRB's conflict of interest policies. When reviewed via expedited review procedures, the Co-Chairperson can take any of the following actions except to disapprove a study.

Specific Policies

Determinations

Approve: The protocol and accompanying documents are approved as submitted. Final approval will commence on the day the study is approved by an action of the convened IRB or Co-Chairperson, and expire within one (1) year of the meeting date, but not later than the day preceding the date of review.

Approve as Amended: Minor modifications of, or additions to, a protocol or attachment are required, and have been made in real time by the IRB. Changes are voted upon during the IRB meeting, as well as the terms of the approval. The Investigator or Document Specialist will be informed in writing (and potentially via E-mail) of the changes made.

Defer: Significant questions are raised by the proposal requiring its reconsideration after additional information is received from the sponsor and/or Investigator.

Disapprove: The proposal fails to meet one or more criteria used by the IRB for approval of research. Disapproval cannot be given through the expedited review mechanism and may only be given by majority vote at a convened meeting of the IRB.

Table: Although on the agenda, discussion does not take place due to lack of expertise or loss of quorum.

APPLICABLE TO:

These policies and procedures apply to all research submitted to the IRB.

RESPONSIBILITY:

The IRB Administrator is responsible for ensuring that all IRB decisions and actions are based on institutional and regulatory requirements.

The IRB Co-Chairperson is responsible for ensuring the appropriateness of all IRB decisions and actions.

APPROVED BY:

President and CEO