

**DECATUR MEMORIAL HOSPITAL
INSTITUTIONAL REVIEW BOARD**

SUBJECT: INITIAL REVIEW OF RESEARCH

STANDARD: PATIENT RIGHTS AND ORGANIZATION ETHICS

EFFECTIVE: 1/98; 04/08

POLICY:

All research proposals that intend to enroll human participants must meet certain criteria before study related procedures can be initiated. The criteria are based on the principles of justice, beneficence, and autonomy as discussed in the Belmont Report and are specified below. In addition, certain other criteria that are unique to Decatur Memorial Hospital may apply and must be met as well.

Specific Policies

Minimal Criteria for Approval of Research

In order for a research project to be approved, the IRB must find that:

1. Risks to participants are minimized
 - By using procedures that are consistent with sound research design and which do not unnecessarily expose participants to risk, and
 - Whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may be expected to result.
 - In evaluating risks and benefits, the IRB will consider only those risk and benefits that may result from the research (as distinguished from risks and benefits of therapies that participants would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effect on the research on public policy) as among those research risks that fall within the purview of its responsibility.
3. Selection of participants is equitable
 - In making this assessment, the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, and pregnant women.
4. Informed consent will be sought from each prospective participant or the participant's legally authorized representative, in accordance with and to the extent required by appropriate local, state and federal regulations.
5. Informed consent will be appropriately documented as required by local, state and federal regulations.
6. Where appropriate, the research plan makes adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
7. When some or all of the participants, such as children, prisoners, or pregnant women are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the study and in the IRB review process to protect the rights and welfare of these participants.
8. Studies are reviewed at periods appropriate to the degree of risk research participants are exposed to due to their participation in the study, but at least annually.

Reliance on Other IRBs for Review and Approval of Research Conducted at Decatur Memorial Hospital

Under authority granted by the Board of Trustees of Decatur Memorial Hospital, the Decatur Memorial Hospital may enter into joint review arrangements, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of efforts as allowed and upon modification of the institutional Federalwide Assurance Agreements (FWA).

APPLICABLE TO:

These policies and procedures apply to the IRB Administrator and the IRB members, and to research submitted to the IRB.

RESPONSIBILITY:

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

IRB Administrator is responsible for providing IRB members adequate submission review training and ongoing guidance, and for selecting primary reviewers to perform reviews and make necessary recommendations on approval decisions by the IRB.

IRB members are responsible for conducting a thorough review and making all appropriate approval recommendations for consideration by the IRB.

APPROVED BY:

President and CEO