

**DECATUR MEMORIAL HOSPITAL
INSTITUTIONAL REVIEW BOARD**

SUBJECT: AUTHORITY OF THE IRB

STANDARD: PATIENT RIGHTS AND ORGANIZATION ETHICS

EFFECTIVE: 1/98

POLICY:

The IRB is an administrative committee of the Board of Directors established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of Decatur Memorial Hospital.

The IRB is guided by the ethical principles regarding all research involving humans as subjects as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled, "The Belmont Report, Ethical Principles and Guidelines for the Protection of Human Subjects of Research."

IMPLEMENTATION:

Upon review of the research, the IRB has the authority to:

- 1) Approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy based upon consideration of human subject protection aspects;
- 2) Suspend or terminate approval of research that is not being conducted in accordance with the IRB requirements or that has been associated with unexpected serious harm to subjects.
- 3) Oversee the conduct of the study and require progress reports from the investigators at intervals appropriate to the degree of risk, but not less than once per year;
- 4) Observe or have the third party observe the consent process and the research.

Decatur Memorial Hospital officials may not approve research if it has not been approved by the IRB.

DOCUMENTATION:

Adequate IRB documentation shall include the following:

- 1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompanies the proposals, approved sample consent documents, progress reports submitted by investigators, and adverse reaction reports.
- 2) Minutes of IRB meeting which show 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 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).
- 3) Records of continuing review activities.
- 4) Copies of all correspondence between the IRB and the Investigators.
- 5) IRB membership roster detailing member qualifications.
- 6) Written procedures and guidelines.
- 7) Statements of significant new findings provided to subjects.

Records shall be retained for at least 3 years, and records relating to research, which is conducted, shall be retained for at least 3 years after completion of the research.

All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner.

APPLICABLE TO:

Except for research in which the only involvement of human subjects is in one or more of the categories exempted or waived under DHHS regulations at 45 CFR 46.101 (b) or 45 CFR 46.101(i), the authority of the IRB applies to all research activities involving human subjects, and all other activities which even in part involve such research, regardless of whether the research is otherwise subject to federal regulation, if:

- a) the research is sponsored by this institution; or
- b) the research is conducted by or under the direction of any employee or agent of this institution in connection with institutional responsibilities; or
- c) the research is conducted by or under the direction of any employee or agent using any property or facility of this institution; or
- d) the research involves the use of this institution's non-public information to identify or contact human research subjects or prospective subjects.

APPROVED BY:

President and CEO