Decatur Memorial Hospital

INSTITUTIONAL REVIEW BOARD
SOP 100: AUTHORITY OF THE DMH IRB

POLICY

The Institutional Review Board (IRB) is an administrative committee of the Board of Directors established to protect the rights, welfare, and safety of human subjects recruited to participate in research activities conducted by or under the auspices of Decatur Memorial Hospital (DMH) and its affiliated members under the Heartland Cancer Research NCORP. The Board of Directors will receive a bi-annual report that summarizes the nature and volume of the IRB activities.

The DMH IRB is guided by the ethical principles of The Belmont Report and the regulations and policies set forth by the Department of Health and Human Services (DHHS) and its subordinate agencies and offices in reviewing all human subjects' research protocols. Therefore, all human subjects research shall be performed in accordance with Title 45 CFR 46, 160 and 164, and Title 21 CFR 50, 56, 312, and 812. In addition, the actions of the Institutional Review Board will also conform to all applicable Federal regulations, state law, and local law.

All human subjects research not reviewed and approved by the National Cancer Institute (NCI) Central IRB shall be reviewed and approved by the DMH IRB prior to the initiation of any research activities, unless another commercial IRB is designated as the IRB of record. As it relates to non-human subjects research, the DMH IRB shall make the determination of exemption or quality improvement/evidence-based practice research.

PROCEDURES

1. Authority Granted

1.1 The DMH IRB shall approve, require modification in (to secure approval), or disapprove all research activities covered by the Common Rule, including exempt research activities for which limited IRB review is a condition.

1.2 The DMH IRB shall suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harms to subjects.

1.3 The DMH IRB shall require that information given to subjects (or legally authorized representatives, when appropriate) as part of informed consent is in accordance with §46.116. The IRB may require that information be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

1.4 The DMH IRB shall require documentation of informed consent or may waive documentation in accordance with §46.117.

1.5 The DMH IRB shall notify investigators in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

1.6 The DMH IRB shall conduct continuing review of research requiring review by the convened IRB at intervals appropriate to the degree of risk, not less than once per year, except as described in Policy 404.

1.7 The DMH IRB shall have authority to observe or have a third party observe the consent process and the research.

1.8 The DMH IRB shall invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB.

2. Limitations

2.1 Neither the DMH Board of Directors nor any other hospital official within the system may approve research if it has not been approved by the DMH IRB.

SCOPE

This SOP applies to DMH officials and the DMH IRB.