

**DECATUR MEMORIAL HOSPITAL
INSTITUTIONAL REVIEW BOARD**

SUBJECT: POLICIES AND PROCEDURES MAINTENANCE

STANDARD: PATIENT RIGHTS AND ORGANIZATION ETHICS

EFFECTIVE: 4/08; 5/09

POLICY:

Following regulations and guidance of OHRP, FDA, and the International Conference on Harmonization (ICH), supported by institutional policies, ensures that the rights and welfare of the human participants of such research will be overseen and protected in a uniform manner, regardless of changes in personnel. Written procedures must be in place to ensure the highest quality and integrity of the review and oversight of research involving human participants and for the adequate documentation of such oversight.

Standard operating policies and procedures (SOPs) provide the framework for the ethical and scientifically sound conduct of human research.

Specific Policies

Review, Revision, Approval of Policies and Procedures

Changes to regulations, Federal guidelines, or research practice as well as the policies and procedures at Decatur Memorial Hospital may require a new SOP or a revision to a previously issued SOP.

Policies will be reviewed by the IRB Administrator at regular intervals.

Approval of new or revised SOPs is required by the hospital Board of Directors, and the signature of the Institutional Official is required.

New or revised SOPs must be presented to the Institutional Review Board.

SOP Dissemination and Training

When new or revised SOPs are approved, they will be disseminated to the appropriate individuals and departments, as well as posted on the DMH IRB web site.

Training will be provided to all IRB Members, Principal Investigators, and Key Study Personnel on any new or revised policy and/or procedure. Evidence of training must be documented and filed in the IRB office.

Each new IRB Member must review all applicable SOPs prior to undertaking any responsibilities on the board. Evidence of training must be documented and filed in the IRB office.

APPLICABLE TO:

These policies and procedures apply to the IRB Administrator at Decatur Memorial Hospital.

RESPONSIBILITY:

The Institutional Official is responsible for granting final approval to new and revised IRB policies.

The IRB Administrator is responsible for establishing and periodically reviewing and modifying IRB standard operating policies and procedures.

APPROVED BY:

President and CEO