Decatur Memorial Hospital

INSTITUTIONAL REVIEW BOARD
SOP 101: POLICIES AND PROCEDURES MAINTENANCE

POLICY
The IRB shall follow regulations and guidance of DHHS, FDA, and Institutional policies to facilitate the protection of the rights, privacy, and welfare of human subjects. The IRB shall oversee, review research, and maintain it in a uniform manner regardless of changes in staff. Written procedures must be in place to ensure the highest quality and integrity of the review and oversight of research involving human subjects and for adequate documentation of such oversight.

SOPs provide the framework for the ethical and scientifically sound conduct of human subjects research. The policies are general statements of principles within the SOPs and provide overall ethical guidance that includes specific detailed directives for their implementation.

PROCEDURES

1. Review, Revision, Approval of Policies and Procedures

1.1 Changes to regulations, federal guidelines, research practice and institutional policies may require a new SOP or a revision to an existing SOP. Changes that affect human subjects research may be identified, in part, by legal counsel, the privacy officer, the Manager of Clinical Research, and the IRB administrator.

1.2 Policies will be reviewed by the IRB administrator at regular intervals; or at a minimum, every 3 years.

1.3 New or revised SOPs must be presented to and approved by the Institutional Review Board. The IRB approval date is the effective date.

2. SOP Dissemination and Training

2.1 When new or revised SOPs are approved, the IRB administrator shall disseminate this information to the research community, and post the documents to the DMH IRB web site.

2.1.1 Training of new or revised SOPs, if necessary, shall be provided by the IRB administrator.

2.1.2 New IRB members and research staff are expected to review all applicable SOPs.

SCOPE
This SOP applies to all IRB members, the IRB administrator, and members of the research community.