

**DECATUR MEMORIAL HOSPITAL
INSTITUTIONAL REVIEW BOARD**

SUBJECT: SIGNATORY AUTHORITY

STANDARD: PATIENT RIGHTS AND ORGANIZATION ETHICS

EFFECTIVE: 4/08; 05/09

POLICY:

The IRB Co-Chairpersons are authorized to sign any and all documents in connection with the review and approval of research projects involving the use of humans as participants, which have been reviewed and approved pursuant to Decatur Memorial Hospital policies and procedures.

IMEDRIS is the system the IRB uses to manage its clinical trials. IMEDRIS is password protected and limited to only those individuals directly connected with the research project and the appropriate regulatory staff. IMEDRIS records the individuals by name and their electronic approval, and all actions taken by those individuals. Some IRB submissions may require outcome letters following their approval. The outcome letters will have digital signatures. The signature of only one of the IRB Co-Chairpersons is required. The signature area on the outcome letter will detail who applied the signature and when this was done.

Specific Policies

Authorization for Signatory Authority

Authorization to sign documents not described in this policy may be made in writing to either IRB Co-Chairperson.

Results of Reviews, Actions and Decisions

The results of review and actions taken by the IRB, either by the full board or by expedited review, that grant or may appear to grant Investigators with initial or continuing approval or research, training or educational projects involving human participants, may be signed by either IRB Co-Chairperson.

Correspondence with External Agencies

Any letters, memos or emails sent to agencies of the Federal government, funding agencies (whether private or public) or their agents will be signed by the Institutional Official, the Director of Clinical Research, or the IRB Administrator.

APPLICABLE TO:

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

RESPONSIBILITY:

The Institutional Official is responsible for establishing the overall procedure for delegating the signatory authority.

The IRB Co-Chairpersons, IRB Members and IRB Administrator are responsible for adhering to institutional signatory authority policies.

The IRB Administrator is responsible for implementing and controlling the signatory authority delegations.

APPROVED BY:

President and CEO