Decatur Memorial Hospital

INSTITUTIONAL REVIEW BOARD
SOP 106: SIGNATORY AUTHORITY

POLICY

The IRB Co-Chair(s) are authorized to sign any and all documents in connection with the review and approval of research projects involving the use of human subjects as participants, which have been reviewed and approved pursuant to Decatur Memorial Hospital's 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-Chairs is required. The signature area of the outcome letter will detail who applied the signature and when this was done. IMEDRIS is a closed system that complies with 21 CFR 11.

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

PROCEDURES

1. Results of Reviews, Actions and Decisions

1.1 The results of reviews 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 of research, training, or educational projects involving human subjects, may be signed by either IRB Co-Chair.

2. Correspondence with External Agencies

2.1 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.

SCOPE

This SOP applies to the IRB Co-Chairs, Institutional Official, Director of Clinical Research, and the IRB administrator.