

**DECATUR MEMORIAL HOSPITAL
INSTITUTIONAL REVIEW BOARD**

SUBJECT: STUDY COMPLETION

STANDARD: PATIENT RIGHTS AND ORGANIZATION ETHICS

EFFECTIVE: 1/98; 05/09

POLICY:

The completion or termination of the study is a change in activity that must be reported to the IRB. Although participants will no longer be “at risk” under the study, submission to the IRB allows the IRB to close its files as well as providing information that may be used by the IRB in the evaluation and approval of related studies.

Specific Policies

Determining When a Project Can be Closed

HHS-supported protocols: When individually identifiable follow-up data are no longer being collected on participants enrolled in an HHS-supported protocol and analysis that could indicate new information is complete, the study may be closed.

Multi-site industry studies may be closed when the Investigator submits his or her submission form. Usually, this is initiated by the research base following a close-out visit.

Study Closure

A change in research activity form should be submitted within 30 days after completion or termination of the study. Attachments may be submitted in any format that provides adequate information about the status of the study, such as computer print-outs, telephone reports, letters, etc. The IRB Administrator will review all reports of study completion and, if needed, request further information from the Investigator to clarify any questions that may arise.

IRB Administrative Closure

If a study is expired and a continuing review submission form or change in research activity form has not been submitted to the IRB, the study will be administratively closed by the IRB. The IRB Administrator will document the reason for the closure in IMEDRIS and a letter to the Investigator will be generated.

Completion Report

A listing of closed studies will be presented to the IRB at the next convened meeting, and copies of the submission form and attachments are made available to the IRB members, upon request.

APPLICABLE TO:

These policies and procedures apply to all research submitted to the IRB.

RESPONSIBILITY:

The IRB Administrator is responsible for ensuring all submission forms are received, reviewed, presented to the IRB, and documented appropriately.

APPROVED BY:

President and CEO