Decatur Memorial Hospital

INSTITUTIONAL REVIEW BOARD
SOP 305: DOCUMENT MANAGEMENT

POLICY

The IRB files will be maintained in a manner that contains a complete history of all IRB actions related to review and approval of a protocol, including continuing reviews, amendments and unanticipated problems. All records regarding a research project will be retained as required by regulatory requirements and hospital policy.

Records will be accessible for inspection and copying by authorized representatives of the sponsor, funding department or agency, regulatory agencies and institutional auditors at reasonable times and in a reasonable manner.

PROCEDURES

1. Study Related Document Retention

1.1 The IRB office will retain all research records and records requiring IRB oversight, whether IRB approved or not, for a minimum of twelve (12) years.

1.2 Adequate documentation on the IRB's activities will be prepared, maintained and retained in a secure location. Retained documents may include:

1.2.1 Submission forms and their respective submission components

1.2.2 Long-term follow-up reports

1.2.3 Agendas and minutes of all IRB meetings

1.2.4 NCORP grant

1.2.5 FDA inspection report (audit results)

2. IRB Administration Document Retention

2.1 The IRB office will maintain and retain all IRB administrative records for a minimum of three (3) years.

2.2 Documents that require maintaining and retaining include:

2.2.1 IRB Rosters

2.2.2 IRB Synopsis

2.2.3 Current and obsolete SOPs

2.2.4 Current and expired Federal Wide Assurances (FWAs)

2.2.5 Current and expired IRB registrations

3. Destruction of Hard Copies

3.1 Since the IRB uses IMEDRIS to manage its clinical trials, there is very limited paperwork at the IRB meetings. To that end, any paperwork left behind in the classroom or conference room will be collected by the IRB administrator and placed in the appropriate bins for destruction.

SCOPE
This SOP applies to all IRB members and the IRB administrator.