

**DECATUR MEMORIAL HOSPITAL  
INSTITUTIONAL REVIEW BOARD**

**SUBJECT:** DOCUMENT MANAGEMENT

**STANDARD:** PATIENT RIGHTS AND ORGANIZATION ETHICS      **EFFECTIVE:** 5/09

**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.

**Specific Policies**

***Study Related Documents & Retention***

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.

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

- Submission forms and their respective submission components.
- Long-term follow-up reports.
- CICCOP grant.
- Agendas and minutes of all IRB meetings.

***IRB Administration Documents & Retention***

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

Documents that require maintaining and retaining include:

- IRB Rosters
- Current and obsolete SOPs.
- Current and expired Federal Wide Assurances (FWAs).
- Current and expired IRB registrations.

***Destruction of Copies***

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 classrooms or conference room will be collected by the IRB Administrator and placed in the appropriate bins for destruction.

**APPLICABLE TO:**

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

**RESPONSIBILITY:**

The IRB Administrator is responsible for maintaining complete records of all research projects and HUDs reviewed by or submitted to the IRB, and for maintaining IRB administrative documents.

The IRB Administrator is also responsible for the proper destruction of IRB documents, as appropriate.

**APPROVED BY:**

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President and CEO