Decatur Memorial Hospital

INSTITUTIONAL REVIEW BOARD
SOP 305: DOCUMENT MANAGEMENT

POLICY

With the advent of software systems, such as IMEDRIS, to help streamline IRB processes and to create a user-friendly environment, the need for document management has changed drastically as it relates to logistics. Document management in the realm of research continues to move away from paper that once required a lot of space to a much more manageable system of review and record retention.

IRB documents of long ago are housed in storage while more recent records can be found mostly in IMEDRIS. IMEDRIS contains a complete history of all IRB actions related to review and approval of a protocol, including initial reviews, amendments, and continuing reviews. IMEDRIS also stores outcome letters, IRB agendas and IRB minutes, and training records.

Some IRB documents are maintained outside of IMEDRIS and can be found in paper form. These documents include our Federalwide Assurance (FWA) and FDA inspection reports.

These documents, many of which require IRB approval, are collectively known as IRB records. IRB records shall 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.

All IRB records shall be retained as required by regulatory requirements and hospital policy.

PROCEDURES

1. Electronic Document Retention

1.1 The IRB office shall provide oversight of IMEDRIS and all documents held therein. All documents requiring IRB oversight, whether IRB approved or not, shall be retained for a minimum of twelve (12) years.

1.1.1 The IRB minutes located within IMEDRIS are not signed by the IRB Co-Chair. Therefore, a printed copy that is signed and dated by the IRB Co-Chair is retained in the IRB Office for inspection. All minutes shall be retained for a minimum of twelve (12) years.

1.2 IRB documents not commonly stored in IMEDRIS shall be maintained for a minimum of six (6) years and stored on the IRB drive where access is limited. This drive is also backed up on a nightly basis. Documents stored on the IRB drive may include:

1.2.1 Current and Expired Federalwide Assurances (FWAs)

1.2.2 Current and Obsolete IRB SOPs

1.2.3 FDA Inspection Reports (audit results)

1.2.4 IRB Rosters

1.2.5 IRB Synopsis

1.2.6 Web Site Information

2. Paper (Hard) Document Retention

2.1 The IRB office shall maintain and retain earlier IRB records (pre-IMEDRIS) for a minimum of twelve (12) years. These records specifically include:

2.1.1 IRB documents by protocol number

2.1.2 IRB agendas

2.1.3 IRB minutes

2.2 These older documents have been catalogued, boxed, and placed in storage.

3. Destruction of Hard Copies

3.1 Catalogued and boxed documents include a destroy date. Documents are destroyed according to schedule.

3.2 Destruction occurs in the form of shredding.

SCOPE

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