

**DECATUR MEMORIAL HOSPITAL
INSTITUTIONAL REVIEW BOARD**

SUBJECT: IRB FILE MAINTENANCE & ACCESS

STANDARD: MANAGEMENT OF INFORMATION

EFFECTIVE: 1/98; 04/04

POLICY: Adequate documentation of IRB activities shall be maintained in accordance with 45 CFR 46.103, 45 CFR 46.115, & 21 CFR 56.115.

IMPLEMENTATION:

The IRB shall prepare and maintain adequate documentation of activities including the following:

- 1) Complete IRB history of all research protocols reviewed, including approved sample consent documents, progress reports/continuing reviews submitted by the investigators, investigator brochures/package inserts or other product information, reports of injuries to subjects, and correspondence.
- 2) Minutes of the IRB meetings which include; attendance, actions taken by the IRB; the vote on these actions, including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving the research; and a written summary of the discussion of controversial issues and their resolution.
- 3) A roster of IRB members in the same detail described in 45 CFR 46.103 (b)(3).
- 4) Written IRB policies & procedures in the same detail as described in 45 CFR 46.103(b)(4)(5).

DOCUMENTATION:

Records required by 45 CFR 46 shall be retained for at least three years, and records relating to research, which is conducted, shall be retained for at least three years after completion of the research.

These records shall be stored in a safe and secure location. After three years, all documents and materials relevant to IRB determinations will be archived according to institutional policy. Archiving policies of Decatur Memorial Hospital will determine when such archived records may be destroyed.

ACCESS:

All records shall be accessible for inspection and copying by authorized representatives of the DHHS, OHRP, FDA, and other legally authorized governing agencies at reasonable times and in a reasonable manner.

Investigators, Clinical Research Staff, and Study Monitors/Sponsors will have access to individual study files for inspection and copying by/through authorized representatives of the IRB staff.

APPLICABLE TO: IRB Records

APPROVED BY:

President and CEO

