

**DECATUR MEMORIAL HOSPITAL
INSTITUTIONAL REVIEW BOARD**

SUBJECT: IRB RECORDS

STANDARD: MANAGEMENT OF INFORMATION
--

EFFECTIVE: 1/98

POLICY: Adequate documentation of IRB activities shall be maintained in accordance with 45 CFR 46.115.

IMPLEMENTATION:

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

- 1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by the investigators, and reports of injuries to subjects.
- 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) Records of continuing review activities.
- 4) Copies of all correspondence between the IRB and the investigators.
- 5) A roster of IRB members in the same detail described in 45 CFR 46.103 (b)(3).
- 6) Written IRB procedures in the same detail as described in 45 CFR 46.103(b)(4)(5).
- 7) Statement of significant new findings provided to subjects.

DOCUMENTATION:

Record Retention:

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.

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

APPLICABLE TO: IRB Records

APPROVED BY:

President and CEO

