

**DECATUR MEMORIAL HOSPITAL  
INSTITUTIONAL REVIEW BOARD**

**SUBJECT:** INFORMED CONSENT MONITORING

**STANDARD:** PATIENT RIGHTS AND ORGANIZATION ETHICS      **EFFECTIVE:** 1/98; 11/03

**POLICY:** To assure that legally effective informed consent is obtained in a manner and method which meets the requirements of 45 CFR 46.116 and 45 CFR 46.117 and the DMH IRB.

**PERFORMED BY:** IRB

**IMPLEMENTATION:**

Documentation of informed consent shall be monitored through review of the informed consent document. This shall be accomplished at:

- 1) Initial review of the research
- 2) Continuing (periodic) review of the research

The following criteria must be met:

- 1) The informed consent document must meet the requirements set forth by the DMH IRB. (See "Informed Consent" Policy/Procedure).
- 2) The most recently DMH IRB approved informed consent document should be presented to the subject or the subject's legally authorized representative.
- 3) The IRB approval date must be current and prior to the subject's (or the subject's legally authorized representative's) date of signature.
- 4) The subject or the subject's legally authorized representative must initial each page of the informed consent document.
- 5) The informed consent document must be concurrently signed and dated by the subject or the subject's legally authorized representative, the investigator or clinical research associate, and a witness.

A voting member of the IRB, appointed by the IRB Chairperson, may monitor presentation of the study information through direct observation of the informed consent process.

Permission to observe the informed consent process must be obtained from the patient and/or the patient's legally authorized representative prior to observation. Any findings shall be reported to the full IRB and the investigator. Considerations to include:

- 1) Was the information understandable?
- 2) Were all elements of the informed consent document covered?
- 3) Was the subject given sufficient time to comprehend the material presented and ask questions?
- 4) Were questions encouraged and answered completely?
- 5) Was the presentation coercive in any manner?
- 6) Was the subject given a signed copy of the informed consent document?

**DOCUMENTATION:** IRB MINUTES

**APPLICABLE TO:** IRB MEMBERS, INVESTIGATORS, and CLINICAL RESEARCH ASSOCIATES

**APPROVED BY:**

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President and CEO