

**DECATUR MEMORIAL HOSPITAL  
INSTITUTIONAL REVIEW BOARD**

<b>SUBJECT:</b> RECONSENTING PATIENTS
<b>STANDARD:</b> PATIENT RIGHTS AND ORGANIZATION ETHICS
<b>EFFECTIVE:</b> 09/06

**POLICY:** To assure protection of the rights and welfare of human research subjects, changes in the informed consent must be reviewed and approved by the IRB prior to implementation, unless the change is necessary to eliminate apparent immediate hazards to the subject. The informed consent document shall comply with the requirements of Federal regulations found in 21 CFR part 50, 45 CFR 46.116, and meet the requirements set forth by the DMH IRB.

No investigator may involve a human being as a subject in research conducted under the auspices of Decatur Memorial Hospital and the Institutional Review Board without first obtaining the legally effective informed consent of the subject or the subject's legally authorized representative.

**IMPLEMENTATION:**

General Requirements

- 1) An investigator or clinical research associate shall seek Reconsenting of a subject when necessary as listed in the guidelines below. In absence of clear directions from the research base or study sponsor regarding informing study participants of protocol changes, a recommendation for Reconsenting will be made by the appropriate clinical research associate and approved by the principal investigator.
- 2) Any time the IRB requests or approves changes to consent documents, it must also determine whether or not study subjects currently enrolled on the studies under consideration must be reconsented. Reconsenting of study subjects can occur in those circumstances when the protocol and the accompanying informed consent document are amended to include additional risks or other important new information such as treatment and/or additional testing must be communicated to the subject.
- 3) In reaching a decision on whether additional risks are significant, the IRB will consider what procedures are taking place during the course of the study; how those procedures are being performed; and at what point in the course of study it would no longer become necessary to reconsent the study subject.
- 4) Reconsenting may occur via oral notification or written communication with the subject. All verbal communication or notifications will be documented by the clinical research associate in the subject's research chart.
- 5) Recommendations may include Reconsenting all patients registered to study regardless of whether or not they are on active treatment. It may include informing a specific subject group, such as only patients on active treatment or on a specific treatment regimen.
- 6) The reconsenting process and the research may be observed by an IRB voting member or a third party appointed by the IRB chairperson.

**DOCUMENTATION:**

Documentation of Reconsenting

- 1) Should the IRB decide that reconsenting study subjects is necessary, it will be communicated in writing to the investigator within 10 days of the IRB's decision. The investigator or clinical research associate will ensure the study subjects are contacted and reconsented in a timely manner.
- 2) Reconsenting shall be documented by the use of a written consent form approved by the IRB and signed and dated by the subject or subject's legally authorized representative and one of the following combinations:

- a) the investigator and clinical research associate
  - b) the investigator and witness
  - c) two clinical research associates
  - d) clinical research associate and a witness
- A copy shall be given to the subject or subject's legally authorized representative signing the form.
- 3) If notifications is done verbally, all verbal communication shall be documented by the clinical research associate in the subject's research chart and will include the following combinations:
    - a) Date and Time the verbal notification was done
    - b) Reason for the notification
    - c) Documentation that the subject understood the reason for the verbal notification
  - 4) In the case that information is sent to the subject regarding the re consent or notification, the following should be documented in the subject's research chart:
    - a) Type of information sent (i.e. letter)
    - b) Date in which the information was sent
    - c) Documentation that the subject received and understood the information regarding a re consent or notification
  - 5) In cases in which the documentation requirement is waived, the IRB may elect to require the investigator to provide subjects with a written statement regarding the research.

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

**APPROVED BY:**

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President and CEO