Decatur Memorial Hospital

**INSTITUTIONAL REVIEW BOARD**
**SOP 413: Informed Consent Monitoring**

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**POLICY**
The DMH IRB may monitor the informed consent process to oversee the progress of the clinical trial, and to ensure that the consent process is carried out in accordance with the protocol, standard operating procedures (SOPs), GCP, and applicable regulatory requirements.

The purpose of consent monitoring is to reduce the possibility of coercion and undue influence by observing the consent process, and to ensure that participants are truly giving informed consent.

**PROCEDURES**

**1. Consent Criteria**

1.1 The following guidelines are to be followed when presenting the consent form to a prospective subject of a clinical trial:

1.1.1 The most recently IRB approved consent form must be presented to the prospective subject, or the subject's legally authorized representative.

1.1.2 The subject or the subject's legally authorized representative and the person obtaining consent should sign and date the consent form in blue ink. Blue ink is preferred over black.

1.1.3 The IRB approval date must be current and prior to the subject's, or the subject's legally authorized representative, date of signature.

1.1.4 The consent form must be signed and dated by the subject or the subject's legally authorized representative, and the person conducting the informed consent discussion. An impartial witness is only required when the participant is illiterate or sight-impaired.

**2. Observing the Consent Process**

2.1 Permission to observe the consent process must be obtained from the subject prior to observation. When observing the consent process, the following key points should be considered:

2.1.1 Whether the informed consent process was appropriately completed and documented

2.1.2 Whether the subject had sufficient time to consider study participation

2.1.3 Whether the information was accurate and conveyed in understandable language

2.1.4 Whether the subject appeared to understand the information and gave their voluntary consent

2.1.5 Whether questions were encouraged and answered completely

**3. When Additional Monitoring May Be Warranted**

3.1 Additional monitoring may be needed if the IRB has concerns that the consent process is not being conducted appropriately or the IRB has identified problems associated with a particular Investigator or a research project.

**4. Post Monitoring**

4.1 Following any consent monitoring, the observer is required to draft a report and submit all findings (good and/or bad) to the IRB administrator who will post the subsequent report to the IRB agenda for review by the full IRB at a convened meeting.

**SCOPE**

This SOP applies to all IRB members, the IRB administrator, and members of the research community.