Decatur Memorial Hospital

INSTITUTIONAL REVIEW BOARD
SOP 406: IRB Actions

POLICY

When reviewing research, the convened IRB is responsible for determining the approval status and appropriate approval period of a study under review when it does not meet the criteria for expedited review. The study approval cannot be for more than a year, and the investigator must be notified in writing of the IRB's determination. All actions will be taken by a vote of a majority of the regular and alternate members present, except for those members present but unable to vote in accordance with the IRB Members' Conflict of Interest policy.

PROCEDURES

1. Possible Actions

1.1 Approve: An IRB action taken when the required determinations are made that allows research involving human subjects to proceed.

1.2 Approve as Amended: An IRB action that requires minor modifications to the consent form/s, and these changes are made in real time by the IRB administrator. The research may proceed.

1.3 Defer: An IRB action taken when the convened IRB has significant concerns or additional questions for the Principal Investigator.

1.4 Disapprove: An IRB action taken when the convened IRB cannot fully evaluate the research under review or the research fails to meet the standards for IRB approval. The DMH IRB will disapprove a study if the rights, welfare, and/or safety of the research subjects are not protected.

1.5 Table: An IRB action taken that indicates the review was not initiated, resulting in postponement of IRB review, usually due to lack of expertise, loss of quorum, or the Principal Investigator was unavailable to present the protocol.

1.6 Withdrawn: An IRB action taken when the review is not necessary, usually when the Principal Investigator does not wish to proceed with the research or when an approved protocol is placed on the IRB agenda in error.

2. Approval Period

2.1 IRB approval will commence on the day the research is approved or approved as amended by an action of either the convened IRB or expedited review.

2.2 The IRB approval may be granted for a period of up to one year.

3. Documentation of IRB Approval

3.1 The study approval date will be documented in IMEDRIS along with the IRB expiration date, unless the research is exempt or deemed quality improvement in which case there is no expiration date.

3.2 All consent documents will contain an IRB approval date and an IRB expiration date, except for the following:

3.2.1 Consent addenda where the patients are informed of new information and would need to affirm their willingness to continue.

3.2.2 Pregnancy release forms or pregnant partner consent forms since neither document is expected to be used on a regular basis.

3.2.3 Withdrawal of consent forms

3.2.4 Protocol-specific revised HIPAA authorizations.

3.3 All study documents will contain the IRB approval date only.

4. Frequency of IRB Review

4.1 Specified time frame

4.2 Requirement to report back to the IRB after a specific number of research subjects have been accrued, though this (re-review) cannot exceed the original specified time frame.

SCOPE

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