Decatur Memorial Hospital

INSTITUTIONAL REVIEW BOARD
SOP 403: Initial Review of Research

POLICY

All research proposals that intend to enroll human participants must meet certain criteria before study-related procedures can be initiated. The criteria are based on the principles of justice, beneficence, and autonomy as discussed in the Belmont Report and are specified below. In addition, certain other criteria that are unique to Decatur Memorial Hospital may apply and must be met as well.

PROCEDURES

1. Minimal Criteria for Approval of Research

1.1 In order for a research project to be approved, the IRB must find that:

1.1.1 Risks to participants are minimized

1.1.1.1 By using procedures that are consistent with sound research design and which do not unnecessarily expose participants to risk, and

1.1.1.2 Whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes

1.2.1 Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may be expected to result.

1.2.1.1 In evaluating risks and benefits, the IRB will consider only those risk and benefits that may result from the research (as distinguished from risks and benefits of therapies that participants would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effect on the research on public policy) as among those research risks that fall within the purview of its responsibility.

1.3.1 Selection of participants is equitable

1.3.1.1 In making this assessment, the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, and pregnant women.

1.4.1 Informed consent will be sought from each prospective participant or the participant's legally authorized representative, in accordance with and to the extent required by appropriate local, state and federal regulations.

1.5.1 Informed consent will be appropriately documented as required by local, state and federal regulations.

1.6.1 When appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of participants.

1.7.1 When appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.

1.2 The IRB must also ensure that:

1.2.1 When some or all of the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these participants.

2. Reliance on Other IRBs

2.1 Under authority granted by the Board of Trustees of Decatur Memorial Hospital, the Decatur Memorial Hospital IRB may enter into joint review arrangements, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of efforts as allowed and upon modification of the institutional Federalwide Assurance (FWA) and a fully executed IRB Authorization Agreement.

2.2 When another IRB is relied upon, the DMH IRB may serve as the privacy board for HIPAA compliance.

3. Possible Outcomes

3.1 The IRB shall review and have authority to approve, require modifications (to secure approval), or disapprove all research activities. Generally speaking, the motions brought forth by the IRB will consist of one of the following:

3.1.1 Approve

3.1.2 Approve as amended, where the IRB administrator makes the changes in real-time and forwards the modified documents to the regulatory compliance coordinator.

3.1.3 Disapprove

3.1.4 Deferred, as a result of major concerns or unanswered questions

3.1.5 Tabled, usually due to a lack of quorum or the principal investigator not being available to present the protocol

3.1.6 Withdrawn. The principal investigator may decide not to proceed with a protocol that has yet to be approved by the IRB.

SCOPE

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