

**DECATUR MEMORIAL HOSPITAL
INSTITUTIONAL REVIEW BOARD**

SUBJECT: DUTIES OF IRB MEMBERS

STANDARD: PATIENT RIGHTS AND ORGANIZATION ETHICS

EFFECTIVE: 5/09

POLICY:

Each IRB Member's primary duty is the protection of the rights and welfare of the individual human beings who are volunteering as research participants. The IRB Member must understand that he or she is not serving on the IRB to expedite the approval of research, but to be a gatekeeper between the Investigator and the research participants. In order to fulfill their duties, IRB Members are expected to be versed in regulations governing human research protection, biomedical research ethics, and the policies of Decatur Memorial Hospital germane to human research protection.

Specific Policies

Duty to Decatur Memorial Hospital

IRB Members serve Decatur Memorial Hospital as a whole, rather than to a particular department. Therefore, IRB Members or ad hoc consultants must not allow their own interest or that of their department to supersede their duty to protect the rights and welfare of research participants.

Term of Duty

There is no set term limit. The IRB Members volunteer their time.

Specific Duties

Non-Affiliated Members: Non-Affiliated Members are expected to provide input regarding their knowledge about the local community and be willing to discuss issues and research from that perspective.

Non-Scientific Members: Non-Scientific Members are expected to provide input on areas germane to their knowledge, expertise and experience, professional and otherwise. For example, members who are lawyers should present the legal views of specific areas that may be discussed, such as exculpatory language or statement requirements regarding consent. Non-scientific members should advise the IRB if additional expertise in a non-scientific area is required to assess if the protocol adequately protects the rights and welfare of participants.

Scientific Members: Scientific Members are expected to contribute to the evaluation of a study on its scientific and statistical merits and standards of practice. These members should also be able to advise the IRB if additional expertise in a non-scientific area is required to assess if the protocol adequately protects the rights and welfare of participants.

Co-Chairpersons: In addition to the above responsibilities (germane to the member's capacity), only one Co-Chairperson will chair the IRB meetings. Submissions that are routed for expedited review can be reviewed by either Co-Chairperson. Both Co-Chairpersons are empowered to suspend the conduct of a clinical trial deemed to place individuals at unacceptable risk, pending IRB review. Both Co-Chairpersons are also empowered, pending IRB review, to suspend the conduct of a study if it is determined that the investigator is not following the IRB's requirements.

- The task of making the IRB a respected part of the Decatur Memorial Hospital research community falls primarily on the shoulders of these two individuals. The IRB must be perceived to be fair and impartial, immune from pressure either by the executive director of the cancer center or by the hospital administration, the investigators whose protocols are being brought before the IRB, or other professional and non-professional sources.

Primary Reviewers: In addition to the duties described above, each regular member will be expected to act as a Primary Reviewer for assigned studies at convened meetings. The Primary Reviewer presents his or her findings resulting from review of the submission material and recommends specific actions to the IRB.

APPLICABLE TO:

These policies and procedures apply to the IRB Members.

RESPONSIBILITY:

The IRB Members are responsible for fulfilling their duties as specified.

The IRB Administrator is responsible for clearly articulating all IRB members' duties to potential and current IRB members.

APPROVED BY:

President and CEO