Decatur Memorial Hospital

INSTITUTIONAL REVIEW BOARD
SOP 203: DUTIES OF IRB MEMBERS

POLICY

The primary duty of each IRB member is the protection of the rights and welfare of the individual human beings who are volunteering as subjects of that research. 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 subjects. In order to fulfill their duties, IRB members are expected to be versed in regulations governing human subjects research protections, biomedical research ethics, and the policies of Decatur Memorial Hospital germane to human subjects research protections.

PROCEDURES

1. Duty to Decatur Memorial Hospital

1.1 IRB members serve Decatur Memorial Hospital as a whole, rather than a particular department. Therefore, IRB members or ad hoc consultants must not allow their own interests or that of their departments, if applicable, to supersede their duty to protect the rights and welfare of research subjects.

2. Term of Service

2.1 Members serve on the IRB at-will for a non-specified length of time. There is no set term limit.

3. Duty of IRB Members

3.1 The task of making the IRB a respected part of the Decatur Memorial Hospital research community falls upon the shoulders of the entire IRB. The IRB must be perceived as fair and impartial, immune from pressure by the Manager of Clinical Research or the Director of Clinical Operations, by hospital officials within the health system, by any investigator whose protocol is being brought before the IRB, or by any other professional or non-professional source.

3.1.1 Non-Affiliated Member(s): The non-affiliated members are expected to provide input regarding their knowledge about the communities in which they serve and be willing to discuss issues and research from that perspective.

3.1.2 Non-Scientific Member(s): The non-scientific members are expected to provide input on areas germane to their knowledge, expertise and experience, professional and otherwise. 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 research subjects.

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

3.1.4 Vulnerable Population Representative: When certain types of research are reviewed, members with specialized knowledge about the concerns of a particular group may be required (e.g. prisoner representative).

4. Primary Reviewer System

4.1 In addition to the duties already described, 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 materials and recommends specific actions to the IRB.

5. Assignments

5.1 Initial Reviews: All IRB members are expected to review each new protocol.

5.2 Amendments: A primary reviewer will be assigned to this type of submission. A second primary reviewer may be requested by the primary reviewer if the submission itself is lengthy and/or complicated.

5.3 Continuing Reviews: A primary reviewer will be assigned to this type of submission. A physician will generally be assigned to humanitarian use devices. The non-scientific members will generally be assigned studies that are closed to accrual, registries, tissue banking, etc.

5.4 Unanticipated Problems: A primary reviewer will be assigned to this type of submission, although all IRB members are expected to review these submissions. Unanticipated problems will be assigned to a scientific member.

SCOPE

This SOP applies to all IRB members and the IRB administrator.