TITLE: Institutional Review Board IRB Organization
OR 203 Duties of IRB Members

POLICY STATEMENT: Each IRB member's primary duty is the protection of the rights and welfare of the individual human beings who are serving as the participant in 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 participant. In order to fulfill their duties, IRB members are expected to be versed in regulations governing human participants protection, biomedical and behavioral research ethics, and the policies of Mercy Health germane to human participants protection. In addition to federal regulations, IRB members should ensure all research conducted at Mercy Health regional sites complies with the CHE Trinity Health Mission, Core Values, and Catholic moral/ethical principles, as delineated in the "Ethical and Religious Directives for Catholic Health Care Services." In this regard, IRB review and decision making gives special consideration for research participants' cultural, racial, social, religious, and economic circumstances.

GENERAL PROVISIONS

Duty to the Institution
The IRB is appointed as an Institutional Committee. As such, IRB members serve Mercy Health as a whole, rather than a particular department. Therefore, members must not allow their own interest or that of their department to supersede their duty to protect the rights and welfare of research participants. All conflicts of interest are to be disclosed at the beginning of each IRB full board committee meeting when requested. All conflicts of interest are also expected to be disclosed during any request for an expedited review.

Term of Duty
Regular IRB members and Chairpersons are expected to commit to a 1, 2, or 3 year term and, during that time, to fulfill certain duties. These duties will be described prior to appointment and each IRB member is expected to fully understand the duties of IRB members prior to accepting appointment as an IRB member. The IRB Chair will determine an IRB members term of duty at the time of their appointment.

Specific Duties
A. Regular Members:
   • Nonaffiliated member(s): Nonaffiliated 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: Nonscientific 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 state requirements regarding consent. Non-scientific members should advise the IRB if additional expertise
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in a non-scientific area is required to assess if the protocol adequately protects the rights and welfare of participants.

B. 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.

C. Chairperson: In addition to the above responsibilities (germane to the member's capacity), the Chairperson is responsible for chairing the meetings of the IRB. Chairpersons perform or delegate to an appropriate voting IRB member expedited review when appropriate. They are empowered to suspend the conduct of a clinical trial deemed to place individuals at unacceptable risk, pending IRB review. The Chairperson is also empowered, pending IRB review, to suspend the conduct of a study if he/she determines that an Investigator is not following IRB's requirements.

The Chairperson may appoint a Co-chairperson or Associate Chairperson or Vice Chairperson to assist or act on behalf of the Chairperson in particular IRB matters and at IRB meetings, either as a general procedure, or on a case-by-case basis. The Chairperson also may delegate any of his/her responsibilities as appropriate to other qualified individual(s). Such documentation must be in writing and maintained by the IRB Coordinator.

The task of making the IRB a respected part of the institutional community will fall primarily on the shoulders of these individuals. The IRB must be perceived to be fair and impartial, immune from pressure either by the institution's administration, the Investigators whose protocols are brought before it, or other professional and nonprofessional sources.

D. Primary and Secondary Reviewers: In addition to the duties described in section 1.3.1, each regular member will be expected to act as a Primary Reviewer for assigned studies at convened meetings. Secondary Reviewers may also be assigned. The Primary Reviewer presents his or her findings resulting from review of the application materials and provides an assessment of the soundness and safety of the protocol and recommends specific actions to the IRB. The IRB Chairperson leads the IRB discussion of the study. The Primary Reviewers may be required to review additional material requested by IRB for the purpose of study approval. The Secondary Reviewers, if assigned, add to the discussion, as necessary.

Attendance
Attendance is required at all IRB meetings unless otherwise excused by the IRB Chairperson. IRB Chairperson has the authority to revoke IRB privileges for non-attendance. A maximum of three meetings per calendar year may be excused.

REFERENCES:
OHRP IRB Guidebook
FDA Information Sheets FAQ, section II, question 17

Attachments:
OR 203-A Member Responsibilities - Regular Member
OR 203-B Member Responsibilities - Chairperson
OR 203-C Member Responsibilities - Special Consultant
OR 203-D Member Responsibilities - Reviewer Duties

PROCEDURE: All Mercy Health Campuses

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<th>Responsibility</th>
<th>Action</th>
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<tr>
<td>IRB Coordinator/ IRB</td>
<td>1. Maintain member responsibilities documents (Attachments OR 203 A-D)</td>
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<td>Specialist</td>
<td>2. Ensure that members are carrying out their expected functions and that there is adequate staff support to ensure that</td>
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IRB Chairperson/IRB Manager

members are able to function as documented.

3. As needed, make recommendations to the Chairperson regarding changes to descriptions, staffing, meeting scheduling, and other factors that affect members' ability to perform their roles.

1. Choose prospective members and touch base with them to discuss expectations.

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1. Meet with IRB Chairperson to discuss expectations of role.

IRB Members

1. Be familiar with responsibilities in the role you are assigned.

2. Disclose any conflicts of interest you may have related to any research you are asked to review.

CONCURRENT CONSENTS:

Institutional Official

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