POLICY STATEMENT: The Mercy Health Regional IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. In addition to federal regulations, all research conducted at Mercy Health regional sites complies with the 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. The IRB should also be able to promote respect for its advice and counsel in safeguarding the rights and welfare of human participants.

Therefore, the IRB shall consist of at least five regular, voting members. Qualified persons from multiple professions and of both sexes shall be considered for membership. IRB membership shall not consist entirely of men or of women. Participation as a member is voluntary. However, Mercy Health RegionalIRB members may be compensated for their activities. The institution will make every effort to have a diverse membership appointed to the IRB, within the scope of available expertise needed to conduct its functions.

1. Membership Selection Criteria

   The members of the IRB shall be sufficiently qualified through experience and expertise, for reviewing research proposals in terms of regulations, applicable law and standards of professional conduct and practice, and institutional commitments. Therefore, the IRB shall include persons knowledgeable in these areas.

   The membership shall be diverse, so selection shall include consideration of race, gender, cultural backgrounds, clinical experience, healthcare experience and sensitivity to such issues as community attitudes to assess the research submitted for review.

   There shall be at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. There shall be one member who has no affiliation with this institution, either self or family member. For FDA-regulated research, there shall be at least one member who is a current licensed physician in the State of Michigan.

2. Composition of the Board

   Regular members: The backgrounds of the regular members shall be varied in order to promote complete and adequate reviews of the types of research activities commonly reviewed by the IRB. Regular members must include:

   A. Nonaffiliated member(s): The nonaffiliated member(s), who can be either scientific or nonscientific reviewers, should be knowledgeable about the local community and be willing to discuss issues and research from that perspective. Consideration should be given to recruiting individuals who speak for the communities from which Mercy Health will draw its research participants. The nonaffiliated member(s) should not be vulnerable to intimidation by the professionals on the IRB, and their services should be fully utilized by the IRB.

   B. Scientific members: Most IRBs include physicians and Ph.D. level physical or biological scientists. Such members satisfy the requirement for at least one scientist. When an IRB encounters studies involving science beyond the expertise of the members, the IRB may use a consultant to assist in the review, as
provided by 21 CFR 56.107(f). However, when FDA regulated products are reviewed, the convened meeting must include a licensed physician member; therefore, at least one (1) member of the IRB must be a physician with a current license in the state of Michigan.

C. Nonscientific member: The intent of the requirement for diversity of disciplines is to include members whose main concerns are not in scientific areas. Therefore, nonscientific members are individuals whose education, work, or interests are not solely in medical or scientific areas.

D. Alternate Members: One or more alternate member may be appointed to fill in for regular members who are on occasion, unable to attend convened IRB meetings. Alternate members must be listed on the IRB's official membership list, which much specify which member (or members) the alternate is qualified to replace. The backgrounds of alternate members should be similar to the member they are replacing or they should be able to represent similar interests. Although an alternate member may be qualified to replace more than one regular member, only one such member may be represented by an alternate member at any convened meeting. Terms of appointment, length of service, and member obligations are the same as for regular IRB members. If both the alternate and the regular member attend a meeting, only the regular member may vote.

E. Representatives of special groups of participants: When certain types of research are reviewed, members or consultants who are knowledgeable about the concerns of certain groups may be required. For example, if an IRB reviews research involving prisoners, a member who can represent this group, either an ex-prisoner or an individual with specialized knowledge about this group must be included on the IRB.

F. Chairpersons: The individual IRB Chairpersons should be highly respected individuals, from within or outside Mercy Health, fully capable of managing the IRB and the matters brought before it with fairness and impartiality. The Institutional Official listed on the FWA for the organization is responsible for selecting and appointing this individual in consultation from the IRB Manager and current IRB Chairperson. The Institutional Official may also request the IRB Committee members recommendations or consult regarding the selection process.

G. Special Consultants: The Chairperson may invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the Board. These individuals may not vote with the regular and alternate members of the IRB and their presence or absence will not be used in establishing a quorum for a Board meeting. Consultants will be used at the Chairperson's discretion, or if requested by the full Board. All consultants will be asked to sign a Conflict of Interest Statement, and consultants with access to confidential information will be asked to sign a Confidentiality Agreement.

The consultant may be asked to participate via a teleconference or attend the Board meeting to lend his/her expertise to the discussions. Consultants will not vote.

H. Resources: The IRB meetings will take place at a Mercy Health location. The filing space, copy machines, computers, etc. will be located in the Office of the Institutional Review Board.

REFERENCE:
45 CFR 46.107
21 CFR 56.107
FDA Information Sheets, FAQ section II, questions 14, 15.

ATTACHMENTS
OR 201-A IRB Membership Roster
## PROCEDURE: All Mercy Health Campuses

<table>
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<tr>
<th>Responsibility</th>
<th>Action</th>
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<tr>
<td>Institutional Official</td>
<td>1. Select and appoint the Institutional Review Board Chairperson in consult with the IRB Manager, current IRB Chairperson and the IRB committee as deemed appropriate.</td>
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| IRB Manager                  | 1. Ensure the overall diversity of the IRB membership (gender, race, ethnicity, community affiliation and professional experience) through non-discriminatory selection methods. May discuss membership with the current IRB chair.  
2. Following established criteria, select new members, and replace members who resign or otherwise leave IRB service. |
| IRB Specialist/IRB Coordinator | 1. Maintain a roster of all regular and alternate members, for FDA inspection purposes. Review IRB Membership Roster on an annual basis to ensure it is current.  
2. Assist in the review and appointment of IRB members to the committee.  
3. Maintain a file on all members, to include their curriculum vita, letters of nomination and other evidence of professional ability.  
4. Review the IRB member files at a minimum every 3 years to ensure documentation on file is current. |
| IRB Chairperson              | 1. Ensure the review process meets all Federal, local and applicable policies.  
2. Serve as a resource to the research community with regard to regulations and expectations for the responsible review and conduct of research activities. |

### CONCURRENT CONSENTS:

Institutional Official  

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