INSTITUTIONAL REVIEW BOARD POLICY & PROCEDURE
Date of Original P&P: 01/10/2014
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TITLE: Institutional Review Board General Administration
       GA 100 IRB Authority, Jurisdiction, Responsibilities and Relationships

ORIGINATOR: IRB Chairperson

APPROVAL: [Signature]

POLICY STATEMENT: Mercy Health believes that research, investigations, or clinical trials involving human subjects demand that our first responsibility is to the health and wellbeing of the individual. To protect and respect patient’s rights, Mercy Health has established an Institutional Review Board (IRB). Subject to FDA and HHS regulations, the IRB is an appropriately constituted group formally designated to review and monitor biomedical and social behavioral research involving human subjects. The purpose of this IRB is to assure, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of human subjects participating as subjects in research.

The IRB is empowered by Mercy Health Board of Trustees to conduct business in accord with FDA and HHS regulations, as well as with the Mission and Values of Mercy Health. 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 reports to the Mercy Health Board of Trustees through the Mercy Health President. The Office of the IRB Personnel reports to the Mercy Health Regional Vice President of Mission Integration.

The Mercy Health Regional IRB reports its findings and actions to the Institutional Official by providing them with meeting minutes. The Mercy Health IRB Manager meets with the Institutional Official on a regular basis to discuss IRB findings, actions, and operational areas of need and growth.

GENERAL PROVISIONS:

AUTHORITY OF THE IRB
The Mercy Health FWA evidences the Mercy Health Regional IRB’s commitment to protecting the rights and welfare of human subjects in accordance with applicable HHS and FDA requirements and the International Conference of Harmonization, Good Clinical Practice and Belmont Report principles. In accordance with the FWA, the Mercy Health Regional IRB has the authority to perform the following tasks:

Risk/Benefit Evaluation: On an initial and on-going basis, provide evaluation of the risks and potential benefits, if any, of research protocols and proposed modifications to research protocols and determine whether the rights and welfare of human subjects are adequately protected thereby. Before any human subject is involved in research under the auspices of Mercy Health, the Mercy Health Regional IRB will give proper consideration to: (a) the risks to the subjects; (b) the anticipated benefits to the subjects and others; (c) the importance of the knowledge that may reasonably be expected to result; and (d) the informed consent process to be employed.
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**Approve or take other voting actions:** See policies and procedures entitled, Research Exempt from IRB Approval, Expedited Review, Initial Review-Criteria for Approval, IRB Meeting Administration, Continuing Renewal-Criteria for Approval, Modifications, Categories of Action, Participant Complaints, Adverse Events, Safety Reports and Serious Adverse Events, Unanticipated Problems, Protocol Deviations and Non-Compliance, Advertisements, Payment to Participants

**Research Protocol Review and Actions:** As described elsewhere in the IRB policies and procedures, the IRB must ensure that each research protocol is ethically and scientifically sound and meets all regulatory requirements. The IRB must provide initial and continuing review and review of modifications to the protocol.

**Report Review:** Review and accept or not accept reports regarding on-going approval for research protocols and based on the review of such reports, permit continuation of the research protocol or require modifications to or discontinuation of the research protocol.

**Protocol Renewal:** Require applications on at least an annual basis for the continuation of approved research protocols and review such applications.

**Research Protocol Oversight:** Oversee the conduct of research protocols to assure compliance with approved protocols and applicable regulations, including the conduct of periodic reviews of research protocols; the conduct of appropriate for-cause, directed, and not-for-cause audits or compliance reviews; the observation of the consent process and the research by the IRB or a third party retained by the IRB to verify that no material changes have occurred since the last approval; the conduct of inquiries into issues or complaints that arise concerning research protocols; and/or the referral of such issues or complaints, or findings regarding such, to other appropriate Mercy Health committees or administrative personnel.

**Suspension, Termination or Restriction of Protocols:** Suspend, place restrictions on, or terminate approval of research activities that fall within the Mercy Health Regional IRB’s jurisdiction that are not being conducted in accordance with IRB requirements or that have been associated with serious harm to human subjects.

**Education/Assistance:** Set training and educational standards for IRB members and for persons who desire to conduct human subjects research under the Mercy Health Regional IRB’s jurisdiction. The Mercy Health Regional IRB also shall provide education, training and assistance to researchers, research staff and students regarding the appropriate and responsible conduct of research.

**Privacy Board Activities Directly Related to Research:** In accordance with the Mercy Health HIPAA Privacy Policies, the Mercy Health Regional IRB is authorized to carry out the specific functions of a Privacy Board related to research under the HIPAA Regulations. The Mercy Health Regional IRB shall carry out the specific functions and responsibilities of a Privacy Board related to research as designated by the Institution’s Privacy Officer, as described in the aforesaid Mercy Health HIPAA Privacy Policies.

**Timing of IRB Review and Approval in Relation to Initiation of Research Protocol:** No protocol for human subjects research and no activities that in whole or in part involve human subjects research (including, but not limited to, interacting with human subjects, human subject recruitment, advertising, or screening for human subject eligibility) may begin unless and until the protocol has been reviewed and approved by the Mercy Health Regional IRB; or a determination has been made that it does not constitute human subjects research or it has been determined as exempt research. In addition, no research activities that involve access to or use of data regarding human subjects that concerns health, health care and/or payment for health care and that contains identifiers, may take place unless and until review and approval by the Mercy Health Regional IRB, acting in its capacity as designated by the Privacy Board, has taken place.

**Failing to Submit a Project for Mercy Health IRB Review:** If a Principal Investigator (PI) fails to submit a project/study for Mercy Health Regional IRB review and the project/study would have qualified as human subjects research subject to Mercy Health Regional IRB review, then the matter will be referred to the Office of the IRB Team or the IRB Committee at a convened meeting. Sanctions to be imposed may be include a determination that data collected for the project prior to obtaining Mercy Health Regional IRB review and approval may not be used for research purposes. (In some cases, the Mercy Health Regional IRB may expressly give permission for research use of the data.)

**After-the-fact Approval Prohibited:** The Mercy Health Regional IRB cannot give after-the-fact approval to a PI who requests Mercy Health Regional IRB approval to continue human subjects research that was initiated without Mercy Health Regional IRB review/approval, nor can it give after-the-fact approval to use data for research that was collected with the intent of
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being used for research without prior Mercy Health Regional IRB approval. In addition, the Mercy Health Regional IRB may not approve research protocols in which it appears that the PI attempted to circumvent IRB review or the policies and procedures by collecting data as non-Research data and then applying to the Mercy Health Regional IRB for use of the data in research. PIs should err on the side of caution and seek Mercy Health Regional IRB review and approval for any project/study concerning or involving human subjects that they believe may fall within the definition of human subjects research, particularly if publication of the project/study is anticipated. Similarly, PIs should seek advance Mercy Health Regional IRB approval for the use of or access to any data concerning health, health care and/or payment for health care that contains identifiers and that the PI believes he/she may want to access/use for human subjects research purposes.

**Further Review of Mercy Health IRB Decisions:** Research that is reviewed and approved by the Mercy Health Regional IRB may be subject to further review, modification or disapproval by officials of Mercy Health or of any other entity that is relying upon the Mercy Health Regional IRB’s review; provided, however, neither Mercy Health, nor any other entity that relies upon the Mercy Health Regional IRB for research protocol review, may interfere with or override a decision of the Mercy Health Regional IRB to disapprove a study, nor may Mercy Health officials approve a research protocol that has been disapproved by the Mercy Health Regional IRB

**JURISDICTION OF THE IRB**

**Scope of Mercy Health Regional IRB Jurisdiction:** With the exception of non-human subjects research and non-clinical investigations, the Mercy Health Regional IRB has jurisdiction over all human subjects research (whether funded or not funded), that is conducted at Mercy Health or that it assumes jurisdiction over per written agreement; or that uses any non-public Individually Identifiable Private Information or Protected Health Information (PHI) maintained by Mercy Health, or any of the components covered under the Mercy Health Federal Wide Assurance (FWA), to identify Human Subjects.

The Mercy Health Regional IRB’s jurisdiction also extends to other entities or individuals who enter into agreements with the Mercy Health Regional IRB per which these entities or individuals subject their research to Mercy Health Regional IRB review. Accordingly, Mercy Health Regional IRB review is required when:

1. The human subjects research is conducted by Mercy Health or any of the components covered by the Mercy Health FWA.

2. The human subjects research is conducted by or under the direction or supervision of Mercy Health or of any employee, faculty member, staff member, student or agent of Mercy Health, or of any of the components covered under the Mercy Health FWA, in connection with that person’s institutional responsibilities or program of education;

3. The human subjects research is conducted by or under the direction or supervision of any employee, faculty member, staff member, student or agent of Mercy Health, or of any of the components covered under the Mercy Health FWA, using Mercy Health property, facilities or resources;

4. The human subjects research uses any non-public individually identifiable private information or Protected Health Information (PHI) maintained by Mercy Health, or any of the components covered under the Mercy Health FWA, to identify human subjects;

5. The human subjects research is conducted by a person who, or entity that, has entered into an agreement with Mercy Health per which the Mercy Health Regional IRB is designated under the Mercy Health FWA as the reviewing IRB for the human subjects research.

**RESPONSIBILITY OF THE IRB**

In order to protect the rights and welfare of persons participating in research, the Mercy Health Regional IRB is responsible for the initial review and continuing oversight of human subjects research under its jurisdiction. Through this review, which includes an initial analysis and on-going monitoring of the risks and benefits associated with the research, the Mercy Health Regional IRB ensures that the human subjects research is being carried out in accordance with the requirements of the applicable HHS and FDA Regulations/Requirements, and the International Conference of Harmonization, Good Clinical Practice and Belmont Report ethical principles.
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In order to ensure that appropriate safeguards exist to protect the rights and welfare of research subjects, the IRB includes within its review all of the research documents and activities that bear directly on the rights and welfare of the subjects of the proposed research, including, but not limited to the following: consent/assent documents, investigational brochure (for studies conducted under the FDA’s Investigational New Drug regulations); tests; surveys; questionnaires; and recruiting documents. The Mercy Health Regional IRB also performs the designated functions of a Privacy Board related directly to research as appointed by the Privacy Board and under the regulations implementing the Health Insurance Portability and Accountability Act.

RELATIONSHIPS

In order to effectively carry out its responsibilities and procedures, the IRB maintains ongoing communication with the Organizational Ethics Team. Additionally, JCAHO regulations regarding patient rights and research are followed. Cooperative research is conducted according to federal regulations and organizational mission and values. Consistent communication is maintained with investigators of research studies, as deemed necessary and appropriate to the nature of the research being done. This is communicated to investigators at the time of approval.

Cooperative Research
Mercy Health has entered into agreement for cooperative research coordinated by a citywide oncology group. The responsibility for initial and continuing review of this research has been delegated to another IRB; this arrangement is documented in letter form, which is kept on file in the Mercy Health Regional Office of the IRB.

Central IRB Use
Mercy Health may use central IRBs for review and ongoing monitoring of any study conducted with Mercy Health patients, staff, or at a Mercy Health location when appropriate. The use of a central IRB will be on a case-by-case basis and is to be determined by the Mercy Health Regional Office of the IRB leadership.

For nonexempt research involving human subjects covered by this policy or exempt research for which limited IRB review takes place at an institution in which IRB oversight is conducted by an IRB that is not operated by the institution, the institution and the organization operating the IRB shall document the institution’s reliance on the IRB for oversight of the research and the responsibilities that each entity will undertake to ensure compliance with the requirements of this policy (e.g., in a written agreement between the institution and the IRB, by implementation of an institution-wide policy directive providing the allocation of responsibilities between the institution and an IRB that is not affiliated with the institution, or as set forth in a research protocol). Mercy Health legal services is responsible for contract and agreement development and negotiation.

EXPLANATION

The IRB Standard Operating Procedures (SOPs) outline the various functions and processes of Mercy Health Regional IRB that meet the guidelines and regulations of the Food and Drug Administration (FDA), the Office of Human Research Protections and other appropriate regulatory agencies. A printed and signed copy of the entire IRB SOPs is located in the Office of the IRB. An electronic copy of the IRB SOPs can be found on Mercy Health website and the Mercy Health Intranet under Policies & Procedures, IRB SOP’s.

REFERENCE:
Mercy Health IRB SOP FO 306
45 CFR Part 46.103; 46.109; 46.111; & 46.112
21 CFR Parts 50 and 56
21 CFR 56.109 & 56.112
38 CFR Part 16, including 16.103(b)(1) – (2); 16.109; 16.111; & 16.112
International Conference of Harmonization http://www.fda.gov/regulatoryinformation/guidances/ucm122049.htm

PROCEDURE: All Mercy Health Campuses

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Version Date 09/12/2018
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<th>Role</th>
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<tr>
<td>Institutional Official</td>
<td>1. Provide IRB Operations report to the Mercy Health Board of Trustees annually at a minimum (and on an as needed basis)</td>
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| Mercy Health Regional Vice President of Mission Integration | 1. Serve as the Executive leader for IRB Operations.  
2. Ensure the Trinity Health Mission, Core Values, and Catholic moral/ethical principles are recognized and applied. |
| IRB Manager                                   | 1. Oversee the day to day operations of the Office of the IRB.  
2. Meet with the Mercy Health Regional Vice President of Mission Integration to report IRB actions, challenges and operational needs.  
3. Meet with Institutional Official to discuss IRB findings, actions and operational needs and growth. |
| IRB Chairperson                               | 1. Apply federal regulations, Institutional Policies and IRB SOPs to the review of research as authorized in this policy.  
2. Serve as a leader and resource to IRB Members. |
| IRB Coordinator                               | 1. Assist IRB Manager and IRB Chairperson in research review, research processing activities and education of IRB Members, Investigators and Study staff as assigned. |
| IRB Specialist                                | 1. Provide administrative support to the Office of the IRB staff, assist in pre-review and processing of submissions, assist in preparation for IRB meeting activity, correspondence issuance and educational activities. |