TITLE: Institutional Review Board Functions and Operations
FO 306 IRB Authority and Institutional Commitment in the Community

ORIGINATOR: IRB Chairperson

APPROVAL: 

POLICY STATEMENT: The policy establishes the provisions under which the Mercy Health Regional Institutional Review Board (IRB) will serve as the IRB of Record for external sites engaged in human subjects research within the community and Mercy Health System. All agreements to establish IRB of Record provisions are to be created, reviewed and approved by the Mercy Health Office of the IRB and Mercy Health Legal Services. In addition to federal regulations, all research conducted at Mercy Health regional sites must comply 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.

GENERAL PROVISIONS:

I. IRB of Record

A. Differences between “coordinating center” and “IRB of Record.”
1. When the Mercy Health Regional IRB serves as the IRB of Record, it is accepting the responsibility of oversight of the conduct of the research for a particular site. The details of such an agreement are outlined in an IRB Reliance Agreement.
2. A “coordinating center” of a multi-center trial is responsible for assuring that IRB approval is granted at the participating sites prior to the initiation of the research at that site. It is important to note that even when an Investigator serves as the “coordinating center,” the Mercy Health Regional IRB may not be the IRB of Record. The coordinating center assumes responsibility for assuring that the participating site has received IRB approval at its site(s).
3. Under rare circumstances, the Mercy Health Regional IRB may be requested to serve as the IRB of Record for a participating site of a multi-center trial in which a Mercy Health Investigator is serving as the “coordinating center.” The participating site may either not have an IRB of Record, or due to other circumstances, may request the Mercy Health Regional IRB to serve as their IRB of Record for that particular study at that particular site.

In an effort to reduce duplicate submission and oversight by multiple IRBs for the same protocol, Mercy Health Regional IRB offers reliance agreement opportunities. IRB Authorization Agreement for Human Subjects Research is an arrangement between institutions allowing the IRB of one institution to reply on the IRB of another institution for review of human subjects research.
A. The Mercy Health Regional IRB will require an IRB Authorization Agreement for Human Subjects Research for any research project in which the Mercy Health Regional IRB will serve as the IRB of record for an unaffiliated Institution.


C. Basis for Mercy Health Regional IRB to serve as the IRB of Record.
   1. The performance site engaged in research does not have an IRB of Record and will rely solely on the Mercy Health Regional IRB for review of human subjects research activities; or
   2. The performance site engaged in research may or may not have an IRB of Record, but will rely on the Mercy Health Regional IRB for a specific research project.

D. Conditions for Mercy Health Regional IRB to serve as the IRB of Record.
   1. The research shall be conducted in collaboration with Mercy Health; and
   2. The Investigator must be an employee of Trinity Health, Mercy Health or Mercy Health Physician Partners and/or credentialed in good standing on the medical staff at Mercy Health and/or;
   3. An IRB Authorization Agreement for Human Subjects Research has been established that designates the Mercy Health Regional IRB as the IRB of Record for a specific project or as agreed upon by the Mercy Health Regional IRB and the requesting organization.

E. The performance site engaged in research requesting Mercy Health Regional IRB to serve as the IRB of Record must:
   1. File a Federal wide Assurance (FWA) for their institution and ensure the Mercy Health Regional IRB is added as an IRB on which they rely; and
   2. Conduct the research in accordance with the terms and conditions specified in the IRB Authorization Agreement for Human Subjects Research established between Mercy Health and their institution.

F. The Investigator must provide all necessary information pertaining to local research activities conducted at external sites in accordance with Mercy Health Regional IRB policies and procedures.

G. The Mercy Health Regional IRB and external site will maintain an approved Federal Wide Assurance (FWA) and provide verification of such during the negotiation of the IRB Authorization agreement and MOU.

H. The Investigator will be responsible for payment of the negotiated fees as established in the IRB Authorization Agreement for Human Subjects Research and in keeping with current Stark Law(s) and regulations.

I. The Investigator and external site will abide by all Mercy Health Regional IRB policies and procedures including accessing the Mercy Health Regional IRB submission system to submit any revisions and/or updates.

J. Investigators will comply with all oversight activities deemed appropriate by the IRB, Federal oversight agencies and/or Federal funding agencies at all sites (e.g., monitoring, auditing).

III. Single IRB Review - Cooperative Research
Cooperative research projects are those projects that involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects.
Institutional Review Board Policy & Procedure

Per federal regulations any institution located in the United States that is engaged in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States. The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research.

The following research is not subject to this provision:
(i) Cooperative research for which more than a single IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe); or
(ii) Research for which any Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context.
(c) For research not subject to paragraph (b) of this section, an institution participating in a cooperative project may enter into a joint review arrangement, rely on the review of another IRB, or make similar arrangements for avoiding duplication of effort.


It is important to remember that an IRB Authorization Agreement for Human Subjects Research for single IRB review are used to cede ONLY IRB review of protocols. All institutionally required ancillary reviews must still be obtained locally. For example, Conflict of Interest, IND/IDE oversight, clinical trial agreements, feasibility, and scientific review.

DEFINITIONS:

**Coordinating Center**: An institution, department, or center, which agrees to be responsible for the conduct, administrative, or coordinating functions of a multi-center research project.

**IRB of Record**: An IRB is considered the IRB of record when it assumes IRB responsibilities for another institution. A Memorandum of Understanding is required designating the relationship.


**Performance Site(s) Engaged in Research**: A performance site becomes "engaged" in human subjects research when its physicians, employees, residents, students and/or agents 1) intervene or interact with living individuals for research purposes, or 2) obtain individually identifiable private information for research purposes. Further, a performance site is considered to be "engaged" in human subjects research when it receives a direct Federal award to support the research.

REFERENCE:
45 CFR 46

ATTACHMENTS:
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<th>Responsibility</th>
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| IRB Manager          | 1. Ensure all submissions received within the Office of the IRB are from an institution of which the Mercy Health Regional IRB serves as the IRB of Record.  
                        2. Ensure copies of all required agreements are fully executed and kept on file in the Office of the IRB.  
                        3. Ensure adequate staffing to cover the quantity of work required to maintain the volume of studies being followed.  
                        4. Provide report of OIRB activity to the Institutional Official on a regular basis so he may provide support when and where needed. |
| Institutional Official| 1. Provide adequate support for needed staffing and materials required to maintain the Office of the IRB at the highest level possible.                                                                   |
| Legal Services       | 1. Develop and execute any necessary IRB Authorization Agreement for Human Subjects Research required to allow the Mercy Health Regional IRB to serve as the IRB of Record or to cede Mercy Health IRB review to another IRB. |