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

ORIGINATOR: Institutional Official

APPROVAL: Institutional Official

POLICY STATEMENT: The policy establishes the provisions under which the Mercy Health Care Institutional Review Board (IRB) will serve as the IRB of Record for external sites engaged in research within the community, Trinity Health system, and Mercy Health System. All agreements to establish IRB of Record provisions are to be created, reviewed and approved by the Mercy Health legal department. 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 a Memo of Understanding (MOU) or an IRB Authorization 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.

II. Memorandum of Understanding (MOU)
   A. An executed MOU may be required if determined by Mercy Health or Trinity Health Legal as the method of establishing the Mercy Health Regional IRB as the IRB of Record for a site, which is not a legal entity of Mercy Health.
   B. The Mercy Health Regional IRB will require an “IRB Authorization Agreement” or an “Unaffiliated Investigator Agreement” (listed on the OHRP website) for any research project in which the Mercy Health Regional IRB will serve as the IRB of record. All agreements for the Mercy Health Regional IRB to serve as the IRB of Record for a performance site “engaged” in research must be detailed in an executed IRB Authorization agreement at a minimum if the site is not listed on the Mercy Health FWA.
   C. If it is determined a MOU is required, the MOU between the relevant parties will outline specific
Institutional Policy & Procedure

provisions and responsibilities for each party entering into the agreement.
D. 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 subject’s research activities; or
   2. The performance site engaged in research may or may not have an IRB of Record, but will rely
      on the specifically designated Mercy Health Regional IRB for a specific research project.
E. 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 and/or Advantage
      Physician Network and/or credentialed in good standing on the medical staff at Mercy
      Health and/or;
   3. An MOU 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.
F. 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
      2. Conduct the research in accordance with the terms and conditions specified in the agreement or
         MOU established between Mercy Health and their institution.
G. 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.
H. 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.
I. The Investigator will be responsible for payment of the negotiated fees as established in the MOU and in
   keeping with current Stark Law(s) and regulations.
J. The Investigator and external site will abide by all Mercy Health Regional IRB policies and procedures
   including accessing Mercy Health Regional IRB submission system to submit any revisions and/or updates.
K. 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).

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.

**Memorandum of Understanding (MOU):** A formal agreement between a specific Mercy Health IRB and another
institution that identifies a specific Mercy Health Institutional Review Board (IRB) as the IRB of record for that
institution.

**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.

**IRB Authorization Agreement:** A written agreement between organizations collaborating in non-exempt human
subjects research that describes each organization’s responsibilities for IRB review and oversight of the research.

REFERENCE:

45 CFR 46

ATTACHMENTS:

FO 306-B Memo of Understanding Template

Version Date 03/17/2016
PROCEDURE: All Mercy Health Campuses

<table>
<thead>
<tr>
<th>Responsibility</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRB Manager</td>
<td>1. Ensure all submission received within the Office of the IRB are from an institution of which Mercy Health IRB serves as the IRB of Record.</td>
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<tr>
<td></td>
<td>2. Ensure copies of all required agreements are fully executed and kept on file in the Office of the IRB.</td>
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<tr>
<td></td>
<td>3. Ensure adequate staffing to cover the quantity of work required to maintain the volume of studies being followed.</td>
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<tr>
<td></td>
<td>4. Provide report of OIRB activity to the Institutional Official on a regular basis so he may provide support when and where needed.</td>
</tr>
<tr>
<td>Institutional Official</td>
<td>1. Provide adequate support for needing staffing and materials required to maintain the Office of the IRB at the highest level possible.</td>
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CONCURRENT CONSENTS:

Signed: ___________________________