INSTITUTIONAL POLICY & PROCEDURE
Date of Original P&P: 09/02/2008
Revision No.: 4
Effective Date 04/14/2016

TITLE: Institutional Review Board Functions and Operations
        FO 304 Administrative Review and Distribution of Materials

ORIGINATOR: Institutional Official

APPROVAL: Institutional Official

POLICY STATEMENT: The efficiency and effectiveness of the Mercy Health Regional IRB is supported by
administrative procedures that ensure that IRB members have adequate time for thorough assessment of each
proposed study and that the documentation they receive is complete and clear enough to allow for an adequate
assessment of study design, procedures, and conditions.

GENERAL PROVISIONS:

1. Exemptions

   The IRB Chairperson or their designee will review Claims for Exemption submitted by Investigators.
   Claims of Exemption that are reviewed and approved by the Chairperson will be logged into the
   IRBManager Database and filed in an IRB book in a manner similar to the procedure followed for
   storage of study documentation.

2. Incomplete Submissions

   Incomplete applications will not be accepted for review until the Investigator has provided all necessary
   materials as determined by the IRB Chairperson or designee. The IRB Chairperson or designee will
   notify the submitting Investigator to obtain any outstanding documentation or additional information
   before the application is scheduled for review.

3. Scheduling for Review

   Complete applications that appear to meet qualifications for expedited review will be provided to the
   Chairperson or designee for review. If a submission meets expedited review requirements, the review
   will be performed as described in SOP RR 401 (Expedited Review). All other applications will be
   placed on the agenda for the earliest meeting possible for review by the full IRB as described in SOP
   FO 303 (IRB Meeting Administration).

4. Distribution to Members Prior to IRB Meetings

   Copies of application materials described in SOP FO 301 (Research Submission Requirements) will be
   made available through the IRBManager database or distributed to all IRB members, generally at least
   ten (10) business days prior to the meeting. Each regular member of the IRB, and any alternate members
   attending the meeting in place of a regular member, will receive a copy of the initial application
   materials. Special consultants will only receive copies of material that pertain to their requested input.
5. Confidentiality
All submitted material received by the IRB will be considered confidential and will be distributed only to meeting participants (regular members, alternate members and special consultants) for the purpose of review. All application materials will be stored in an IRB study file and the IRBManager Database with access limited to IRB members and staff. Consultants and visitors will be expected to sign an IRB Confidentiality Agreement.

REFERENCE:
21 CFR 56.109
45 CFR 46.109

PROCEDURE: All Mercy Health Campuses

<table>
<thead>
<tr>
<th>Responsibility</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRB Specialist/IRB Coordinator</td>
<td>1. Communicate with investigators to gather any additional materials as needed for review.</td>
</tr>
<tr>
<td></td>
<td>2. Communicate with IRB Members for expected attendance at the IRB meeting. Assemble IRB member packets and distribute accordingly.</td>
</tr>
</tbody>
</table>

CONCURRENT CONSENTS:
Institutional Official

Signature

Version Date 04/14/2016