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.
Institutional Policy & Procedure

The originals of submission materials will be retained in the Office of the IRB and are available for the IRB meeting.

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

Institutional Official

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