INSTITUTIONAL POLICY & PROCEDURE
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Revision No.: 5
Effective Date 05/01/2016

TITLE: Institutional Review Board Functions and Operations
FO 303 IRB Meeting Administration

ORIGINATOR: Institutional Official

APPROVAL: Institutional Official

POLICY STATEMENT: Except when an expedited review procedure is used, the Mercy Health Regional Institutional Review Board (IRB) will review proposed research at convened meetings at which a quorum is present. The IRB will meet monthly, or at some other frequency determined by the IRB Chairperson and the IRB Manager. In addition to federal regulations, IRB members should ensure 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.

GENERAL PROVISIONS:

1. Quorum
   1.1.1 A quorum is defined as one half of the number of regular members plus one. A quorum must be present to approve or disapprove a study.
   1.1.2 A quorum consists of regular members and includes: at least one member whose primary concerns are in scientific areas, and one member whose primary concerns are in nonscientific areas.
   1.1.3 When FDA-regulated research is reviewed, there shall be one member who is a physician.
   1.1.4 An alternate member may attend in the place of an absent regular member in order to meet the quorum requirements outlined above.
   1.1.5 A special consultant(s) will not be used to establish a quorum.
   1.1.6 If a member abstains from voting, the member may still be used to establish a quorum.
   1.1.7 If a member recuses him/herself from deliberations and voting, the member may not be used to establish quorum for the duration of review of the item from which the member is recused. A member experiencing a COI must recuse him/herself.
   1.1.8 The IRB Chair counts in determining the meeting quorum, but does not vote, except to break a tie. (OHRP – Chapter 8; Section B-3)

2. Primary Reviewers
   Prior to the meeting, the Chairperson will designate primary reviewers for each research proposal. The primary and secondary reviewer’s duties are described in SOP OR-203.

3. Meeting Materials Sent Prior to IRB Meetings
   All IRB members will be provided with study documentation required for review sufficiently in advance of the meeting to allow time for adequate review. These include:

Version Date 04/13/2016
1.3.1 Agenda: A meeting agenda will be prepared by the IRB Specialist and distributed to IRB members prior to each meeting. A copy of the agenda and attached materials will be maintained on file with the meeting minutes.

The meeting agenda will remind members to declare any potential COI they may have with research that is about to be reviewed at the outset of each meeting. The Chairperson will ask for a declaration of such conflict and this will be incorporated in the minutes of the meeting. The IRB minutes should also specifically reflect such recusals as they occur during meetings.

1.3.2 Reviewer materials

A. All IRB members
   - Full Investigator’s or Sponsor’s protocol
   - A completed IRB Application with a signature page.
   - Proposed informed consent document(s) and HIPAA documentation as appropriate
   - Copies of surveys, questionnaires, videotapes, DVD’s, and audiotapes
   - Copies of letters of assurance or cooperation with research sites
   - All other submitted materials are available to IRB members through the IRBManager electronic portal

B. Primary reviewers
   - Full Investigator’s or Sponsor’s protocol
   - A completed IRB Application with a signature page
   - Proposed informed consent document(s) and HIPAA documentation as appropriate
   - Copies of surveys, questionnaires, videotapes, DVD’s, and audiotapes
   - Copies of letters of assurance or cooperation with research sites
   - Advertising intended to be seen or heard by potential participants, including e-mail solicitations and physician letters
   - Protocol Review Worksheet: Primary Reviewer (RR 402-A) and Informed Consent Form Checklist (IC 701-A).
   - Grant Application: The primary reviewers may review the grant application, if any, to ensure that the research described in the IRB proposal is consistent with the grant application. The grant application does not need to be reviewed by every IRB member. A copy of the proposal should be retained by IRB Office and made available to any IRB member who may wish to review it. The IRB may require the Investigator(s) to: (i) summarize, and cross-reference to the application, specific information contained in the grant application; (ii) identify any IRB-approved protocols that describe the proposed research; and (iii) either certify that the application or proposal is consistent with any corresponding IRB protocol(s) or submit protocol amendments to reconcile any discrepancies.
   - IRB Review of NIH-Approved Informed Consent Documents for NIH-Supported Multicenter Clinical Trials: If available, for NIH-supported multi-center clinical trials the IRB must receive and review a copy of the NIH-approved sample informed consent document and the full NIH-approved Investigator’s protocol as a condition for review and approval of the local informed consent document. Any deletion or substantive modification of information concerning risks or alternative procedures contained in the sample informed consent document must be justified in writing by the Investigator, approved by the IRB, and reflected in the IRB minutes.

4. Minutes
The Federal regulations for the protection of human participants [45 CFR 46.115(a)(2)] require that "Minutes of IRB meetings... shall be in sufficient detail to show attendance at the meeting; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution." These requirements are minimal.

However, Mercy Health does not believe it can be assumed that all regulatory requirements for review of research have taken place at an IRB meeting unless the IRB minutes reflect that they were considered
and discussed. Good minutes should enable a reader who was not present at the meeting to determine exactly how and with what justification the IRB arrived at its decisions.

1.4.1 Recording: The IRB Specialist or designee will take minutes of each meeting using IRB Minutes Template (Form FO 303-B). Minutes will be written in sufficient detail to show the following:

- Meeting attendance; including status of each attendee (regular member, consultant, etc.), and conflicts of interest, if any;
- Actions taken by the IRB on each agenda item requiring full IRB action, including, the basis for requiring changes in or disapproving the research;
- Summary of the discussion of controverted issues and resolution;
- Voting results, including number for, against and members who recused themselves and reason for recusal.

1.4.2 Approval: Draft minutes will be distributed to members at the next IRB meeting for review and approval.

- Corrections requested by the IRB will be made by the IRB Specialist or designee and the minutes will be printed in final form and made available to members at the following meeting. The Chairperson of the IRB shall sign and date final, approved minutes.
- The IRB Coordinator and/or IRB Specialist will maintain copies of the minutes, as well as the agenda and pertinent materials on file (see SOP FO 305).

A majority of members must vote in favor of an action for that category of action to be accepted by the IRB. Only regular and alternate members acting in place of absent regular members may vote. The vote will be recorded in the minutes. Members with a conflict of interest will recuse themselves from the discussion and voting and such will be noted in the minutes.

5. Telephone Use

1.5.1 Convened meeting using speaker phone:

Should a member not be able to be physically present during a convened meeting, but is available by telephone, the meeting can be convened using a speakerphone. The member who is not physically present will be connected to the rest of the members via speakerphone. In this manner, all members will be able to discuss the protocol even though one member is not physically present. Members participating by speakerphone may vote, provided they have had an opportunity to review all the material the other members have reviewed.

1.5.2 Meetings Conducted Via Telephone Conference Calls:

On occasion, meetings may be convened via a telephone conference call. A quorum (as defined above) must participate for the conference call meeting to be convened. To allow for appropriate discussion to take place, all members must be connected simultaneously for a conference call to take place -- "telephone polling" (where members are contacted individually) will not be accepted as a conference call.

Members absent from the convened meeting and who do not participate in the conference call may not vote on an issue discussed during a convened meeting (no voting by proxy).

6. Voting

Members of the IRB vote upon the recommendations made by the primary reviewers according to the criteria for approval (see SOP RR 402). Members also will determine level of risk, the frequency of review for each protocol, monitoring of the investigative site, and whether third party assessment and follow-up will be needed.

ATTACHMENTS:
FO 303-A IRB Agenda Template
FO 303-B IRB Minutes Template
Institutional Policy & Procedure

REFERENCE:
45 CFR 46.103, 46.108
21 CFR 56.108, 56.109
FDA Information Sheets, 1998

PROCEDURE: All Mercy Health Campuses

<table>
<thead>
<tr>
<th>Responsibility</th>
<th>Action</th>
</tr>
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<tbody>
<tr>
<td>IRB Coordinator/IRB Specialist</td>
<td>1. Create agenda using the IRB Agenda Template.</td>
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<tr>
<td></td>
<td>2. Assemble reviewers' packets per SOP FO 304</td>
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<td></td>
<td>3. Attend meeting of the IRB. Use IRB Minutes Template to record proceedings of the meeting.</td>
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<td>4. Provide IRB members with summary of expedited reviews conducted and serious adverse event reports received since the last IRB meeting.</td>
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<tr>
<td>IRB Chairperson</td>
<td>1. Using the IRB Agenda Template as a guide, chair meeting. Ensure that all business is addressed, that proceedings are recorded, and that any member who has a conflict of interest does not participate in the IRB's consideration of the study for determination, except as requested by the IRB, nor in voting.</td>
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<tr>
<td>IRB Specialist</td>
<td>1. Complete draft minutes in time to include in the reviewers' packets for the next meeting.</td>
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CONCURRENT CONSENTS:

Institutional Official

Signature