TITLE: Institutional Review Board Review of Research RR 408 Categories of Action

ORIGINATOR: Institutional Official

APPROVAL: Institutional Official

POLICY STATEMENT: As a result of its review, the IRB may decide to approve or disapprove the proposed research activity, or to specify modifications required to secure IRB approval of the research activity. Except when the expedited review procedure is used, these actions will be taken by a vote of a majority of the regular and alternate members present, except for those members present but unable to vote in accordance with IRB's conflict of interest policies. When reviewed via expedited review, the Chairperson or designee can take any of the following actions except to disapprove a study.

GENERAL PROVISIONS:
The IRB may make one of the following determinations as a result of its review of research submitted for initial review or for continuing review:

A. Approval: The protocol and accompanying documents are approved as submitted. Final approval will commence on the day the study is approved by an action of the convened IRB or Chairperson or designee and expire within one (1) year of the meeting date, but not later than the day preceding the date of review.

   Approvals are always considered conditional. The conditions for continued approval, and the time frame (if any) within which they must be met will be clearly stated in the approval letter. If the conditions of the approval are not met, approval may be withdrawn.

B. Withheld Approval: Minor modification of, or addition to, a protocol or accompanying document(s) is required. Changes will be voted upon during IRB's meeting, as well as the terms of approval. The Investigator will be informed in writing of the required changes and requested information and must provide the IRB with the changes or information.

   The IRB Chairperson or his/her designee has the authority to review the information via expedited review unless the IRB requires that the material or information be reviewed by the full IRB, the primary reviewer or another individual delegated by the IRB to review the response. Upon satisfactory review, approval will be issued as of the date that the requested information or materials are approved. However, the expiration date of IRB approval will be based on the anniversary date of the initial IRB review. Participants must not be recruited into the study until final approval has been issued.

C. Tabled: Significant questions are raised by the proposal requiring its reconsideration after additional information is received from the Sponsor and/or Investigator.

D. Disapproval: The proposal fails to meet one or more criteria used by the IRB for approval of research. Disapproval cannot be given through the expedited review mechanism and may only be given by majority vote at a convened meeting of the IRB.
Institutional Policy & Procedure

Voting Actions

Each IRB member may vote "For", "Against", "Abstain" or "Recuse"

Voting "For" an item: This means the investigator is not required to change any aspect of the protocol or informed consent document. The approval is valid for one year unless the committee designates a shorter period due to the risk of the study.

Voting "Against" an item: This means the magnitude or number of concerns, questions or problems is such that the full IRB committee must review a new study application. The study written as is does not meet the federal criteria for approval and would not be deemed safe and responsible to conduct.

Recuse: This means and IRB member has a conflict of interest with any part of the study, the IRB member should not participate in the initial or continuing review of the study except to provide information requested by the IRB. He or she must leave the room and not participate in the vote. This is considered a recusal and will not be counted as part of the voting quorum. Conflicts of interest include financial interest, active participation in the trial as principal investigator, sub-investigator, key study personnel or any issue for which the member feels his or her vote could be considered potentially conflicted.

Abstain: This means an IRB member does not have a conflict but feels that he or she should not vote on a study. A vote to abstain will be included as part of the voting quorum. An abstention vote should be a rare event. The typical reason an IRB member abstains from voting is when he or she was not present for the discussion of an important issue. When an IRB member has been present for the discussion of the major issues, but is still not comfortable with voting on an item then he or she should register a not approved vote or vote "Against" an item.

REFERENCE:
21 CFR 56.109-113
45 CFR 46.109
45 CFR 46.115

PROCEDURE: All Mercy Health Campuses

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<th>Responsibility</th>
<th>Action</th>
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<tbody>
<tr>
<td>IRB Specialist/IRB Coordinator</td>
<td>1) Document IRB decisions in the minutes</td>
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<td></td>
<td>2) Distribute notifications of IRB decisions in a timely manner.</td>
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<tr>
<td>IRB Chairperson</td>
<td>1) Review and sign all IRB decision letters.</td>
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CONCURRENT CONSENTS:
Institutional Official [Signature]

Version Date 01/22/2015