TITLE: Institutional Review Board Review of Research
RR 401 Expedited Review

ORIGINATOR: Institutional Official

APPROVAL: Institutional Official

POLICY STATEMENT: An expedited review process consists of a review of research involving human participants by the Chairperson of the IRB or by one or more experienced reviewers designated by the Chairperson from among members of the IRB. The criteria for approval are applied when reviewing proposed minimal risk studies. Studies must meet the expedited review criteria as outlined in 45 CFR 46.110 and 21 CFR 56.110. In addition to federal regulations, 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.

The categories of research that may be reviewed by the IRB through an expedited review process include research activities that (1) present no more than minimal risk to human participants, and (2) involve only procedures listed in one or more of the specific categories listed in the regulations at Federal Register Volume 63, No 216.

GENERAL PROVISIONS:
1.1 Definition of Minimal Risk
Minimal risk is defined as "...the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests...."

1.2 Cautions
1.2.1 The activities listed should not be deemed to be of minimal risk simply because they are included on the list of eligible research. Inclusion on this list merely means that the activity is eligible for review through the expedited review process when the specific circumstances of the proposed research involve no more than minimal risk to human participants.

1.2.2 The expedited review process may not be used where identification of the participants and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal. Furthermore, the expedited review process may not be used for classified research involving human participants.

1.3 Authority of the IRB Chairperson
The IRB Chairperson (or designated reviewer) may exercise all of the authorities of the IRB, except that he/she may not disapprove the research. A research proposal may be disapproved only after review by the full IRB.
Institutional Policy & Procedure

1.4 Notification of the IRE
When the expedited review process is used, all regular members shall be informed of actions taken by the IRB at the next convened meeting.

1.5 Documentation
If the study qualifies for expedited review, the IRB Chairperson or designee will document his/her determination of risk on the expedited review worksheet.

The minutes will include documentation of the studies that were reviewed via expedited review and any issues resolved relating to questions that IRB members had concerning the research reviewed.

1.6 Additional Items That May be Reviewed by the Chairperson or Designee

1.6.1 Conditional approval pending minor revisions, clarification: Revisions to consent documents and other documentation or clarifications submitted as a result of full IRB review and as a condition to final approval may be reviewed by the IRB Chairperson or his/her designee. Final approval will be issued providing the revisions, documentation or clarifications do not indicate or result in a change to the study or change the risk/benefit ratio.

1.6.2 Continuing review

The IRB Chairperson may use the expedited review process to review minor changes in previously approved research during the period for which approval is authorized. Any protocol revision that entails more than a minimal risk to the participants must be reviewed by the full IRB at a convened meeting.

Revisions to informed consent documents: Minor changes to informed consent documents that do not affect the rights and welfare of study participants, or do not involve increased risk or significant changes in study procedures may be reviewed and approved by the Chairperson/designee. (refer to policy RR 403 and RR 406)

Serious adverse event and safety reports: A designated SAE/AE/IND safety report subcommittee will triage serious adverse event reports (including IND safety reports) according to pre-established criteria. The Chairperson will review those reports deemed significant. If the Chairperson feels that action is needed to protect the safety of research participants due to the nature or frequency of reported adverse events, he/she may take such action to the full IRB or designated subcommittee, which will review the adverse events and study in question to determine action, if any, by the IRB. The IRB Chairperson acting for the IRB will review summaries of safety reports and serious adverse events as soon as possible. (refer to policy RR 404 and RR 405)

Advertisements: The IRB Chairperson, or his/her designee may approve new or revised recruitment advertisements or scripts (refer to policy RR 409).

1.6.3 Translations: Translations of consent documents will also be submitted for IRB approval and will be reviewed in an expedited manner. There are two options available to obtain approval of translated consent forms.

Option #1: The IRB-approved consent form is translated by the Sponsor or site and submitted to the IRB. Investigators must submit documentation of translator qualifications or a certification that the translation was done to the best of the translation groups abilities. Translator must be from a qualified translation interpreter service. The consent form must match the English version.

Option #2: The Investigator (or Sponsor) may submit the IRB-approved version of the consent to an IRB-approved, certified translator and must submit documentation of translator qualifications or a certification that the translation was done to the best of the translation groups abilities.

Translation costs will be the responsibility of the investigator or sponsor. The IRB is not responsible for any translation costs.

REFERENCE:
45 CFR 46.102
21 CFR 56.102
45 CFR 46.110
21 CFR 56.110
FDA Information Sheets, 1998
OHRP IRB Guidebook
http://www.hhs.gov/ohrp/policy/expedited98.html
Institutional Policy & Procedure

http://www.hhs.gov/ohrp/policy/exprev.html
http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm118099.htm

ATTACHMENTS:
RR 401-A Expedited Review Worksheet
RR 401-B Guidance – Expedited Review
RR 401-C Notice of IRB New Expedited Approval with ICF
RR 401-D Notice of IRB New Expedited Approval with waiver

PROCEDURE: All Mercy Health Campuses

**Expedited Review—New Study**

**Responsibility**
IRB Specialist/IRB Coordinator

**Action**
1. Make initial determination regarding qualification for expedited review. Refer to Guidance as needed.
2. If the study qualifies for expedited review, work with chairperson to assign reviewer. Chair may choose to review or assign a designated reviewer.
3. Notify IRB Chairperson or designated reviewer that a new study is ready to be reviewed.
4. Provide review materials to the assigned reviewer with notification of review deadline.
5. After review is complete, add item to the next IRB meeting agenda.
6. Upload review documentation into the IRBManager electronic study portal.
7. Issue correspondence as advised by the IRB Chairperson.
8. Provide the agenda and supporting meeting materials to IRB members prior to the next IRB meeting.

IRB Chairperson or designee

1. IRB Chairperson to perform review or designate primary reviewer.
2. Document result of review using Expedited Review Worksheet (RR 401-A and RR 402-A)
3. Upon completion of the review, provide study review materials, completed checklists and worksheets to the IRB Specialist.
4. Advise IRB Specialist of the correspondence to be issued.

**Expedited Review—Continuing Renewal**

**Responsibility**
IRB Chairperson or designee

**Action**
1. Perform review or designate primary reviewer.
2. Ensure the Criteria for Approval continues to be met.
3. Advise IRB Specialist of the correspondence to be issued.
Expedited Review – Modifications

Responsibility
IRB Chairperson or designee

Action
1. Perform review and make determination regarding qualification for expedited review. Refer to guidance as needed.
2. Advise IRB Specialist of correspondence to be issued.

IRB Specialist/IRB Coordinator

1. If the modification qualifies for expedited review, assemble reviewer's material and provide to IRB Chairperson or designated reviewer.
2. Notify reviewer that a new modification is ready to be reviewed.
3. Upon completion of the review, issue correspondence and add the modification to the next IRB meeting agenda.
4. Provide the agenda and supporting meeting materials to IRB members prior to the next IRB meeting.