TITLE: Institutional Review Board Review of Research
RR 402 Initial Review-Criteria for IRB Approval

ORIGINATOR: Institutional Official

APPROVAL: Institutional Official

POLICY STATEMENT: All research proposals that intend to enroll human participants must meet certain criteria before study-related procedures can be initiated. The criteria are based on the principles of justice, beneficence and autonomy as discussed in the Belmont Report and are specified below. In addition, certain other criteria that are unique to the Mercy Health system may apply and must be met as well. While the IRB must ensure the study meets the federal regulations of the Criteria for Approval, it may disapprove a study if it determines a research study is so methodologically flawed that little or no reliable information will result, as it is unethical to put subjects at risk or even inconvenience them through participation in such a study.

GENERAL PROVISIONS:

1. Minimal Criteria for Approval of Research
   In order for a research project to be approved, the IRB must find that:

   A. Risks to participants are minimized:
      • By using procedures that are consistent with sound research design and which do not unnecessarily expose participants to risk, and
      • Whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.

   B. Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may be expected to result.
      • In evaluating risks and benefits, the IRB will consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies that participants would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

   C. Selection of participants is equitable.
      • In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons.

   D. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with and to the extent required by appropriate local, state and federal regulations.
E. Informed consent will be appropriately documented as required by local, state and federal regulations.

F. Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants.

G. Where appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.

H. When some or all of the participants, such as children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons, are likely to be vulnerable to coercion or undue influence or for participants found at international sites, additional safeguards have been included in the study and in the IRB review process, to protect the rights and welfare of these participants.

I. Studies are reviewed at periods appropriate to the degree of risk research subject are exposed to due to their participation in the study, but at least annually.

J. In order to protect against financial conflicts of interest or perceived conflicts of interest, all principal investigators must complete a conflict of interest form at the time of initial protocol submission and with each reapproval request.

K. In addition, if the research study involves an investigational new drug or a significant risk device, the additional requirements set forth in the federal regulations 21 CFR 312 - Investigational New Drug (IND) Applications must be satisfied.

1.2 Other Criteria

The IRB may require verification of information submitted by an Investigator. The purpose of the verification will be to provide necessary protection to participants when deemed appropriate by the IRB.

The criteria used to determine whether third-party verification is required may include:

- Investigators that conduct studies that involve a potential high risk to participants,
- Studies that involve vulnerable populations,
- Investigators that conduct studies that involve large numbers of participants, and
- Investigators selected at the discretion of the IRB.

Projects that need third party verification from sources other than the Investigator that no material changes have occurred since previous IRB review is determined, will have such assessment performed as necessary.

2. Reliance on Other IRBs for Review and Approval of Research Conducted at Mercy Health.

Under authority granted by the Board of Trustees of Mercy Health, the Mercy Health IRB(S) may enter into joint review arrangements, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort as allowed and upon modification of the institutional Multiple Project Assurance/Federal-wide Assurance agreements (MPA/FWA).

3. Types of IRB Review

There are three types of IRB review: Exempt, expeditable and full board.

The required qualifications and process for Exempt Research is outlined in IRB SOP FO 302. The required qualifications and process for expeditable research is outlined in IRB SOP RR 401.

All research studies that do not meet the criteria for expedited review or exemption will be reviewed by the full IRB committee at a convened IRB meeting with a quorum present. Principal investigators will be invited and required to attend meetings at which their proposals are being presented to provide a brief study description and answer any questions or concerns that may arise from committee members. Mercy Health requires the principal investigator to attend as having an investigator present during the meeting allows the IRB members to gauge the investigators knowledge of the study, address IRB member concerns on any aspect of the trial, and answer IRB member questions. Having an investigator at a meeting allows for quick resolution of some questions/issues and helps avoid the need to delay review and approval for an issue or concern that could likely be resolved by their presence.

Prior to the IRB meeting, a statistical, scientific and informed consent reviewer is assigned by the IRB Chairperson to review the initial application submission package. Each reviewer is provided with the appropriate checklist and asked to return their review and comments within 10 days of receiving the request to review.
Institutional Policy & Procedure

Once the reviewers comments have been returned, the comments are forwarded to the principal investigator and they are asked to respond to the reviewer in writing as quickly as possible. The study coordinator or investigator may submit revised study materials based on the reviewers comments during this review phase. The reviewer is asked to communicate with the Office of the IRB throughout the pre-review process in order to keep the Office of the IRB staff aware of what is occurring with regard to discussion and revisions. Reviewers are asked to confirm in writing that all concerns have been appropriately addressed as requested. If all concerns are not addressed the reviewer must provide a summary of all outstanding concerns to the Office of the IRB staff prior to the IRB meeting at which the study will be presented and discussed.

The IRB may also request verification from other sources that no material changes have occurred since study submission. If the IRB determines it is necessary to do so, they will outline the specific steps to be taken in IRB meeting minutes and an individual or group will be assigned to complete the task.

REFERENCE:

45 CFR 46.111
21 CFR 56.108, 56.111

ATTACHMENTS

RR 402-A  Protocol Review Worksheet: Primary Reviewer
RR 402-B  Hold for Future Use
RR 402-C  Informed Consent & HIPAA Review Worksheet
RR 402-D  Notice of IRB Approval- with ICF
RR 402-E  Notice of IRB Approval-with waiver
RR 402-F  Notice of Minor Revisions Requested to IRB Submission
RR 402-G  Notice of Disapproved Study
RR 402-H  Notice of Tabled Protocol
RR 402-I  IRB Status Request

PROCEDURE: All Mercy Health Campuses

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<th>Action</th>
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<td>IRB Chairperson</td>
<td>1. Select reviewers with appropriate expertise for the research to be reviewed.</td>
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<td>2. Ensure all reviewers findings have been addressed and prepare to discuss reviewer findings with the IRB Committee.</td>
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<td>3. Inform IRB Coordinator/IRB Specialist of outcome and the proper correspondence to be issued.</td>
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<td>IRB Coordinator/IRB Specialist</td>
<td>1. Provide primary and secondary reviewers with appropriate protocol review worksheets.</td>
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<td>2. Upload completed worksheets into the IRB Manager system when they are returned.</td>
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<td>3. Provide the completed forms to the Investigator for review and response.</td>
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<td>4. Issue correspondence as advised by the IRB Chairperson.</td>
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<td>IRB Member or Designated Reviewer</td>
<td>1. Review research proposal and summarize findings on appropriate protocol review worksheet.</td>
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<td>2. Ascertain whether any special considerations exist that may influence the review of a proposal.</td>
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Version Date 08/20/2015
3. Ascertain whether the evidence exists that third party verification of submitted information is needed.
4. Prepare summary of findings and recommendations for presentation at the next convened IRB meeting.
5. Return review materials and recommendation documentation to the IRB Chairperson.
6. Upon request of the IRB Chair, communicate with the investigator to resolve reviewer findings.
7. Provide Chairperson with documentation of reviewers satisfaction with investigators response to reviewers comments.
8. If reviewers findings are not addressed by the investigator, reviewer is to inform the chair of outstanding findings that still need to be addressed.

IRB Committee

1. Review the proposed research and all submitted materials.
2. Be prepared to debate issues and to make difficult determinations that are required to meaningfully influence the protection of human research participants.
3. Vote for, against, abstain or recuse the research proposal during the IRB meeting.

Investigator

1. Attend the IRB meeting as requested.
2. Present an overview of the study to the IRB committee as requested.
3. Be prepared to answer any questions or concerns raised by IRB members during conduct of the IRB meeting.
4. Make requested changes and provide the IRB with updated documentation as requested.
5. Submit additional documentation requested by the IRB committee.
6. Store copies of all IRB submissions and correspondence in an organized manner in a regulatory binder.

CONCURRENT CONSENTS:

Institutional Official