INSTITUTIONAL REVIEW BOARD POLICY & PROCEDURE

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Revision No.: 5
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TITLE: Institutional Review Board Review of Research
RR 406 Continuing Renewal

ORIGINATOR: IRB Chairperson

APPROVAL: IRB Chairperson

POLICY STATEMENT: The IRB conducts continuing review of research taking place within its jurisdiction at intervals appropriate to the degree of risk, but not less than once per year. 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.

GENERAL PROVISIONS:

1. Interval for Review for Purposes of Renewal
   The IRB must conduct continuing review of protocols for purposes of renewal of the IRB approval period, at intervals appropriate to the degree of risk, which is determined at the initial review, but not less than once per year. "Not less than once per year" means that the research must be reviewed on or before the one-year anniversary of the previous IRB review date, even though the research activity may not have begun until sometime after IRB gave its approval.

   Investigators or qualified designees are required to submit a periodic report prior to the expiration of the study or as specified by the IRB, but at least annually. The report should normally be filed 60 days before the study approval period ends.

   Unless the IRB determines otherwise, continuing review of research is not required in the following circumstances:
   (i) Research eligible for expedited review in accordance with 45 CFR 46.110;
   (ii) Research reviewed by the IRB in accordance with the limited IRB review described in 45 CFR 46.104(d)(2)(i)(ii), (d)(3)(ii)(C), or (d)(7) or (8);
   (iii) Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:
       (a) Data analysis, including analysis of identifiable private information or identifiable biospecimens,
       or
       (b) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

2. Extensions of Approval Period
   There is no grace period extending the conduct of the research beyond the expiration date of IRB approval. Extensions beyond the expiration date will not be granted. If Continuing Review Report forms and other requested progress reports are not received as required, the Investigator must
suspend the study and study enrollment until reports are reviewed and approved. Study suspensions due to lack of continuing review must be reported to the FDA and OHRP as required by federal regulations.

However, if the investigator is in communication with the IRB, the Continuing Review Report or other report is forthcoming, and in the opinion of the IRB, participants participating in such a study would suffer a hardship if medical care were discontinued, appropriate medical care may continue beyond the expiration date for a reasonable amount of time. However, new participants cannot be enrolled. The IRB will address on a case-by-case basis those rare instances where failure to enroll new participants would seriously jeopardize the safety or wellbeing of an individual. Prospective research data cannot be collected, and no procedures that are only being performed for the purposes of the protocol may be performed until a Continuing Review Report or other progress report is reviewed and approved.

3. Criteria for Renewal

Continuing review must be substantive and meaningful. When considering whether or not to renew a study, the IRB revisits the same criteria for approval used to grant initial approval. Therefore, the IRB (or the reviewers for protocols reviewed under an expedited procedure) must determine that:

- The risks to participants continue to be minimized and reasonable in relation to the anticipated benefits;
- The selection of participants continues to be reasonable in relation to anticipated benefits;
- Informed consent continues to be sought and appropriately documented;

Additionally, there are:

- Provisions for safety monitoring of the data,
- Protections to ensure the privacy of participants and confidentiality of data, and
- Appropriate safeguards for vulnerable populations.

The IRB may also request verification from other sources that no material changes have occurred since the prior review. 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.

For each identified study, determine whether to continue to comply with the pre-2018 common Rule, or elect to comply with the 2018 Common Rule

Because it may be only after research has begun that the real risks can be evaluated and the preliminary results used to compute the actual risk/benefit ratio; IRB can then determine whether or not the study can be renewed at the same risk/benefit ratio, or if new information has changed that determination.

In order to determine the status of the study, the following will be revisited:

- Consent document: Each member of the IRB shall review the currently approved consent document and ensure that the information is still accurate and complete. Any significant new findings that may relate to the subject’s willingness to continue participation should be provided to the subject in an updated consent document.
- Study progressing as planned
- Current approved protocol including any amendments to protocol since initial review: A copy of the protocol will be made available to the primary reviewer of the continuing review. Amendments and addenda to a research protocol should be submitted as generated during the course of the study. They also may be submitted at the time of continuing review. A separate cover letter describing the change and all appropriate documentation (approved consent form) must accompany the continuing review application.
- Continuing review of DSMB-monitored clinical trials: When a clinical trial is subject to oversight by a DSMB whose responsibilities include review of adverse events, interim findings and relevant literature (e.g., DSMBs operating in accordance with the National Cancer Institute Policy for Data and Safety Monitoring of Clinical Trials), the IRB conducting continuing review may rely on a current statement from the DSMB indicating that it has
reviewed study-wide adverse events, interim findings and any recent literature that may be relevant to the research, in lieu of requiring that this information be submitted directly to the IRB. However, the IRB must still receive and review reports of local, on-site unanticipated problems involving risks to participants or others and any other information needed to ensure that its continuing review is substantive and meaningful.

- Any new information that has become available that indicates a need for study modification
- Progress report: All IRB members shall receive a progress report prepared and submitted by the Investigator along with the number of participants entered to date and since the last review. The progress report shall summarize adverse event experiences, amendments, changes in training of personnel and new COI disclosure as applicable, and provide a reassessment of the risk-to-benefit ratio.

4. Possible Outcomes of Continuing Review

As an outcome of continuing review, the IRB may require that the research be modified or halted altogether. The IRB may need to impose special precautions or relax special requirements it had previously imposed on the research protocol.

There must be documentation of rationale if the IRB will conduct continuing review when not otherwise required.

5. Expedited Review for Renewal

When conducting research under an expedited review procedure, the IRB Chairperson or designated IRB member conducts the review on behalf of the full IRB using the same criteria for renewal as stated in this policy. If the reviewer feels that there has been a change to the risks or benefits, he or she may refer the study to the full IRB for review.

REFERENCE:

21 CFR 56.108,111
45 CFR 46.111


FDA Guidance-Suspension or Termination of IRB approval
https://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ReportProblemsToFDA/ucm136102.htm

Guidance on Reporting Incidents to the Office for Human Research Protection (OHRP)

ATTACHMENTS:

RR 406-A Continuing Renewal Application
RR 406-B Notice of IRB Expedited Renewal Approval-with waiver of informed consent
RR 406-C Notice of IRB Expedited Renewal Approval-closed to enrollment
RR 406-D Notice of IRB Expedited Renewal Approval with informed consent
RR 406-E Notice of IRB Suspension
RR 406-F Notice of Full Board Renewal Approval-closed to enrollment
RR 406-G Notice of Full Board Renewal Approval-no icf
RR 406-H Notice of Full Board Renewal Approval with ICF
RR 406-I Continuing Renewal Worksheet Full Board
PROCEDURE: All Mercy Health Campuses

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| IRB Specialist/IRB Coordinator | 1. The IRBManager electronic notification system is set up to auto remind investigators of the need for continuing renewal. Email notifications are automatically generated at 90, 60, 30, and 14 days prior to study approval expiration. Additional manual follow-up may be necessary.  
2. Send out continuing review packets to reviewers as assigned.  
3. Place incoming continuing renewal forms on the next IRB meeting agenda after it has been confirmed that all needed documentation for review has been received.  
4. Provide chairperson with review summaries.  
5. After study has been evaluated and approved for continuing renewal, generate appropriate letter (e.g. continuing renewal approval letter) and provide to investigator(s). |
| IRB Chairperson:          | 1. Familiarize self with all incoming continuing renewal requests for next IRB Meeting agenda.  
2. Review and approve or disapprove all expeditable continuing renewal requests.  
3. Prepare to discuss continuing renewals at next full board meeting  
4. Issue Notification of Study Suspension if a study lacks submission for continuing renewal within the required timeframe. |
| Assigned Reviewer         | 1. Review the continuing renewal package and all study documentation.  
2. Provide IRB Chair with summary of review and outline if the study continues to meet the criteria for approval. |
IRB Members

1. Review the submitted continuing renewal package/materials. Determine if the study continues to meet the criteria for approval.
2. Vote when indicated during the IRB meeting. Be prepared to determine the length of the approval. Typically approvals are for 6 or 12 month periods.