MCW IRB Committee Procedures

REVIEW OF CONTINUING PROGRESS REPORTS (CPR)

Unit: Human Research Protections Program (HRPP), Office of Research

Applies to: MCW Institutional Review Board Committees

PURPOSE:
This procedure outlines the steps taken when a Continuing Progress Report (CPR) submission will be reviewed by a Convened Committee and the expectations of the IRB member assigned as the primary reviewer.

MCW IRB has two (2) IRB committees focused on the review of minimal risk research. Continuing review of minimal risk projects which appear to qualify for expedited review, or an exempt determination is outlined in *IRB Member SOP: Review of Exempt or Expedited Review*

DEFINITIONS:
N/A

POLICY:
CONTINUING REVIEW

1. The IRB Committee conducts continuing review of a project at intervals appropriate to the identified degree of risk, but not less than once per year unless they meet the following criteria.
    a. The project was initially determined to be no greater than minimal risk
    b. The project does not receive or is not supported by federal funding
    c. The project does not fall under FDA regulations
    d. The project does not have an inter-institutional agreement on file deferring IRB review to the MCW IRB from another institution.
2. The IRB Committee considers a CPR submission a summary of activities that have been conducted since receiving initial IRB approval or previous continuing review approval.
    a. The CPR will be reviewed in accordance with regulatory and institutional requirements.
3. The IRB Committee will review and examine the Principal Investigator (PI) and project staff to ensure that their expertise and training is appropriate to conduct the research.
4. The standards for the review of a CPR submission and/or consent form(s) are outlined in the *IRB Member Form: CPR Reviewer Checklist* which includes the federal regulations criteria for approval (45 CFR 46.111 and/or 21 CFR 56.111). These forms are available to IRB members via the HRPP website and during the meeting.
    a. For projects which were initially reviewed by a convened Committee and now qualify for expedited review, reviewers will document their decision via the *Staff: IRB Coordinator II Checklist for CPR*.
        i. For projects that do not require continuing review, reviewers will document their rationale for conducting a continuing review.

ii. For projects that appear on the expedited review list, reviewer's will document their rationale for determining that the research is more than minimal risk.

5. The IRB Committee applies the same standards and criteria for re-approval as used for the initial approval of the project as described in *IRB Member SOP: Initial Review and Primary Reviewer Responsibilities*.
6. Additional criteria for the review of research which may involve minors, prisoners, pregnant women and fetuses or individuals who may be decisionally impaired are applied as set forth in the following procedures:
    a. *IRB Member SOP: Research Involving Prisoners*
    b. *IRB Member SOP: Research Involving Pregnant Women and Fetuses*
    c. *IRB Member SOP: Research Involving Children*
    d. *IRB Member SOP: Research with Subjects Likely to Manifest or Develop Decreased Decisional Ability*

The specific criteria for approval are made available to all members via the HRPP website and during the meeting.

Convened Meetings and the Primary Reviewer System

1. The MCW IRB Committees uses the same "primary reviewer" system at continuing review as used at initial review.
2. The Primary Reviewer performs an in-depth review of all the information included in the continuing progress report submission for which they are assigned, including the complete protocol and any protocol modifications previously approved by the IRB. The review is conducted according to the standards outlined in the *IRB Member Form: CPR Reviewer Checklist* as appropriate.
    a. This checklist is available via the HRPP website.
3. All other IRB committee members are expected to review key documentation from the information submitted to the IRB committee to the extent necessary to be prepared to participate in the discussion of the regulatory criteria for approving research, in accordance with *IRB Member SOP: Conduct and Expectation of IRB Members*
    a. For continuing review of a project and Investigator "key documentation" includes the following:
        i. eBridge CPR SmartForm
        ii. Consent Form(s)
        iii. Recruitment materials (if provided)
        iv. Protocol deviation logs, safety reports or summaries, sponsor communications, etc.
        v. Multi-site information as indicated in *IRB Member SOP: Multi-site Projects and Coordinating Center Responsibilities.*
4. If the assigned Primary Reviewer, the IRB Chair or HRPP director determines that additional expertise is needed for the review, an appropriate consultant will be invited to assist in the review of the research in accordance with *IRB Member SOP: Assigning Reviewers and the Use of Consultants.*
5. Following the presentation, the Primary Reviewer makes a motion for the IRB Committee's vote as outlined in *IRB Member SOP: IRB Actions* and opens the floor for discussion among the members. At the end of the discussion the IRB Chair will call for a vote.
    a. The Primary Reviewer's motion will include the length of approval for the project. The Primary Reviewer will review the criteria for identifying projects which may require review on a more frequent basis as outlined in this procedure.

Research that Does Not Require Continuing Review

Research meeting the following requirements does not require continuing review unless otherwise determined by the IRB:

- Research eligible for expedited review under 45 CFR 46.110
- Research determined to meet exempt criteria and reviewed by limited IRB review.
- Research that involves only one or both of the following in accordance with the IRB-approved project:
    - Data analysis, including analysis of identifiable private information or biospecimens
    - Accessing follow-up clinical data from procedures that are part of routine care

If the IRB determines that continuing review is required even though a project meets the above conditions, the reviewer will document the rationale for conducting continuing review on the *IRB Member Form: CPR Reviewer Checklist*.

If the CPR required convened committee review, the rationale will also be recorded in the minutes.

Suspension or Termination at the Time of Continuing Review:
The Committee may vote to suspend or terminate a project at any point throughout the life of a project, including at the time of continuing review. Additional information about suspension or termination can be found in *IRB Member SOP: IRB Actions.* The reasoning behind the Committee's suspension or termination may include, but is not limited to, the following:

1. If it comes to the Committee's attention that additional unapproved activities have occurred during the previous reporting period, the Committee can vote to suspend the project and request an audit by the MCW HRPP QA/QI Office.
2. If the Committee determines at the time of continuing review that the information from the previous reporting period represents a significant increase in risk which outweighs the benefits of the project, the Committee may either suspend the project pending additional information or terminate the project.

Research Reviewed more than Annually
The IRB Committee is required to review research at least once per year, unless the project meets the specific criteria described earlier in this policy. The Primary Reviewer or other Committee members may suggest/recommend a shorter frequency of review in circumstances including, but not limited to, the following:

1. The risk-benefit ratio is such that the IRB committee should review project data and progress at a shorter interval to determine if the research is still acceptable
2. High-risk of harm and/or a high likelihood that harm may occur

REFERENCES:
45 CFR 46.110
45 CFR 46.111
21 CFR 56.111

SUPPORTING DOCUMENTS:
IRB Member SOP: Initial Review and Primary Reviewer Responsibilities
IRB Member SOP: Research with Subjects Likely to Manifest or Develop Decreased Decisional Ability
IRB Member SOP: Multi-site Projects and Coordinating Center Responsibilities
IRB Member SOP: Research Involving Prisoners
IRB Member SOP: Research Involving Pregnant Women and Fetuses
IRB Member SOP: Research Involving Children
IRB Member SOP: Conduct and Expectation of IRB Members
IRB Member SOP: Assigning Reviewers and Use of Consultants.
IRB Member SOP: IRB Actions
IRB Member Form: CPR Reviewer Checklist
IRB Member Form: Expedited Approval Form
IRB C2 CPR Checklist

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