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.

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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