MCW IRB Committee Procedures

REVIEW OF 6-YEAR RENEWALS

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

Applies to: Institutional Review Board Committees

PURPOSE:
This procedure outlines the steps taken when a 6-Year Renewal submission will be reviewed by the convened Committee and the expectations of the IRB members assigned as the primary reviewers.

MCW IRB has two (2) IRB committees focused on the review of minimal risk research. Continued review of projects including 6-year renewal submissions 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

PROCEDURE:
6-Year Renewals
1. The IRB Committee considers the 6-Year Renewal submissions as a renewal to the project to update the described activities which have been conducted since receiving initial IRB approval. A 6-Year Renewal submission will be reviewed in accordance with current regulatory and institutional requirements.
2. The IRB Committee will review and examine the Principal Investigator (PI) and project staff to ensure that their expertise and training remains appropriate to conduct the research.
3. The standards for the review of a 6-Year Renewal and/or consent form(s) are outlined in the *IRB Member Form: 6-Year Renewal 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.
4. 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*.
5. Additional criteria for the review of research which may involve minors, prisoners, pregnant women and fetuses or individuals who may be decisional 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 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 with 6-Year Renewals as used at continuing review.
2. The assigned Primary Reviewer performs an in-depth review of the 6-Year Renewal application, which includes both review of the continued progress report and modified eBridge PRO SmartForm and currently approved documents.
3. The assigned Primary Reviewer will compare the two versions of the project and will look specifically for changes and modifications as well as the modified or updated project to confirm it meets all criteria for approval according to the standards outlined in the *IRB Member Form: 6-Year Renewal Checklist*.
4. 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 6-Year Renewal of a project and Investigator "key documentation" includes the following:
        i. eBridge CPR SmartForm
        ii. Modified eBridge SmartForm including section 53
        iii. Consent Form(s) if still open to enrollment
        iv. Recruitment materials (if still open to enrollment)
        v. Protocol deviation logs, safety reports or summaries, sponsor communications, etc.
        vi. Multi-site information as indicated in *IRB Member SOP: Multi-site Projects and Coordinating Center Responsibilities.*
5. 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 *Staff: Assigning Primary Reviewers and the Use of Consultants.*
6. 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.

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

1. The IRB Committee is required to review research at least once per year, unless the project meets specific regulatory criteria described in *IRB Member SOP: Review of Continuing Progress Reports (CPR)*.
2. The Primary Reviewer or other Committee members may suggest/recommend a shorter frequency of review in circumstances including, but not limited to, the following:
    i. 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.
    ii. High risk of harm and/or a high likelihood that harm may occur.

REFERENCES:

N/A

SUPPORTING DOCUMENTS:

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: IRB Actions
IRB Member SOP: Initial Review and Primary Reviewer Responsibilities
IRB Member SOP: Review of Exempt or Expedited Review
IRB Member SOP: Assigning Reviewers and Use of Consultants.
IRB Member Form: 6-Year Renewal Checklist

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