AMENDMENTS

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

Applies to: Institutional Review Board Committees

PURPOSE:
This procedure outlines the steps taken when an amendment will be reviewed by the MCW IRB either by expedited review or convened Committee and expectations of the IRB members assigned as primary and/or secondary reviewers.

MCW IRB has two (2) IRB committees focused on the review of minimal risk research. Review of project submissions (including amendments) 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:
REVIEW OF AMENDMENT

1. At the time of review, the IRB Committee considers an amendment as a description of the changes to the approved project to be reviewed in accordance with regulatory and institutional requirement.
    a. If the proposed changes are to change the Principal Investigator, the IRB Committee will review and examine the new Principal Investigator (PI) and project staff as components of the research to ensure the expertise and training to complete the research is appropriate.
2. The standards for the review of an amendment submission and/or revised consent form are outlined in the *IRB Member Form: Amendment Reviewer Checklist* which contains the federal regulations criteria for approval (45 CFR 46.111 and/or 21 CFR 56.111).
    a. These forms are available to members via the HRPP website, and during the meeting.
3. The IRB Committee must determine if the following criteria are still met for approval of the changes.
    a. Risks to subjects are minimized by using procedures which are consistent with sound research design, and which do not unnecessarily expose subjects to risk and whenever appropriate by using procedures already being performed on the subject for diagnostic0 Trenprgauresmponentasd iformievrel regnsaridofnefits,5.9(a)5.5(sy,a.)-xpos

e. Informed consent is appropriately documented or if approved by the IRB waived. See: *IRB Member SOP: Informed Consent for Human Subject Research*
f. When appropriate, data will be monitored to ensure the safety of subjects. *See IRB SOP: Data and Safety Monitoring Plans.*

5. New risks or new information regarding risks

Other Federal Agencies Requirements:

1. For projects that receive funding from or based upon the nature of the project, may be subject to additional federal agency-specific requirements. The following must be applied and considered during the review process:
    a.

5. All other IRB Committee members are expected to review key documentation from the information submitted to the IRB Committee in the amendment submission to the extent necessary to be prepared to participate in the discussion of the regulatory criteria for approving research as described in *IRB Member SOP: Conduct and Expectation of IRB Members*
    a. For review of an amendment submission "key documentation" includes the following:
        i. SmartForm application
        ii. Consent Form (if applicable)
        iii. Recruitment materials (if provided)
6. If the assigned Primary Reviewer, the IRB Chair or HRPP Director determines that additional expertise is needed for the proposed research, 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.*
7. 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.
8. At the end of the discussion the IRB Chair will call for a vote.

REFERENCES:
45 CFR 46.111
21 CFR 56.111

SUPPORTING DOCUMENTS:
IRB SOP: Requirements for Reporting to the IRB
IRB Member SOP: Informed Consent for Human Subject Research
IRB Member SOP: Privacy and Confidentiality
IRB Member SOP: Research Involving Prisoners
IRB Member SOP: Research Involving Pregnant Women and Fetuses
IRB Member SOP: Research Involving Children
IRB Member SOP: Research with Subjects Likely to Manifest or Develop Decreased Decisional Ability
IRB Member SOP: Conduct and Expectation of IRB Members
IRB Member SOP: IRB Actions
IRB Member SOP: Assigning Reviewers and Use of Consultants.
IRB Member Form: Amendment Reviewer Checklist
IRB C2 AME Checklist

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