MCW IRB Committee Procedure

REVIEW OF EXEMPT AND EXPEDITED PROJECTS

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

Applies to: Institutional Review Board Committees

PURPOSE:
Per *MCW Corporate Policies: Research Involving Human Subjects and/or their Private Identifiable Information (RS.HS.010)* and *Human Research Protection Program (RS.HS.040),* the MCW IRB is charged with reviewing all research governed by the MCW Human Research Protection Program (HRPP) to determine if it meets applicable ethical standards and other requirements of this policy and the HRPP. In carrying out these duties the MCW HRPP Office is authorized to make the following determinations for research involving humans.

1. The HRPP Office will determine whether the proposed research satisfies the definition of human subjects research as defined under the federal regulations. Not Human Subjects Research (NHSR) Determinations are finalized by HRPP Office staff.
    a. For research that engages Children's Wisconsin, the Children's Wisconsin HRPP will make NHSR determinations.
2. For research that satisfies the definitions of human subjects research, the IRB Committee will determine if:
    a. The proposed research is exempt from federal human research subjects protection regulations.
    b. The proposed research is minimal risk and qualifies for expedited review.
    c. The proposed research is more than minimal risk and requires review by the convened IRB.

All determinations will be made in accordance with the applicable federal regulation and guidance, and each determination and its basis will be documented and communicated to Investigators.

This procedure outlines the steps taken for a new project submission, continuing progress report or amendment will be reviewed by IRB Committee members and the expectations of the IRB members assigned as primary and/or secondary reviewers which meet the definition of minimal risk as defined by the federal regulations.

DEFINITIONS:
Research: a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether they are conducted or supported under a program which is considered research for other purposes. For example: some demonstration and service programs may include research activities.

Clinical Investigation: any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the

Food and Drug Administration under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit.

- The term does not include experiments that are subject to the provisions of part 58 of this chapter, regarding nonclinical laboratory studies.

Human subject –

1. **(HHS regulations):** A living individual about whom an investigator (whether professional or student) conducting research:
   a. Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens, or
   b. Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

   In this definition, the following terms are defined as:
   - *Intervention* includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
   - *Interaction* includes communication or interpersonal contact between investigator and subject.
   - *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).
   - *Identifiable private information* is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
   - *An identifiable biospecimen* is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen. (45 CFR 46.102)
2. **(FDA regulations):** An individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient. (21 CFR 56.102)

Not Human Subjects Research (NHSR): Projects that do not fit the definition of research, do not actively involve human subjects, do not access private, identifiable human data, and are not purposed to support the marketing of an FDA-regulated drug, biologic, or device product.

Minimal Risk: the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Minimal risk projects may not require review at a convened meeting.

- A research project cannot be determined to be minimal risk unless all research activities are determined minimal risk.

Exempt Research*:* DHHS regulations have defined broad categories of research that are "exempted" from IRB review if they meet conditions detailed in 45 CFR 46.104.

- FDA regulations define very limited exemptions from the IRB requirements in 21 CFR 56.104.

Expedited Review: A process of research review conducted by either the IRB chair or an experienced IRB member or group of members *also referred to as "designated*

reviewer" rather than at a convened IRB meeting. Federal rules permit expedited review for certain kinds of research involving no more than minimal risk and for minor changes in approved research [45 CFR 46.110 and 21 CFR 56.110].

PROCEDURE:
The IRB Chair or designated reviewer reserves the right to forward any proposed research to a convened meeting for review if they determine the proposed research does not meet the criteria established or is determined to be more than minimal risk.

New Protocol Review:
1. Investigators will complete and submit an initial eBridge PRO SmartForm for the IRB to review. The eBridge PRO SmartForm is completed for both Expedited and Exempt submissions.

2. An IRB Coordinator II (C2) will review the eBridge SmartForm, completing the appropriate C2 checklist and confirming necessary documents are uploaded for the review of the project, including:
    a. Protocol Summary
    b. Consent Form(s) or consent documents (such as informational letters, or scripts)
    c. Recruitment materials (if provided)
    d. Data Collection Sheets (if applicable)
    e. Questionnaires, surveys, interview scripts
    f. Any grant application or contract
    g. Agreements such as Data Use Agreements (DUA) or Material Transfer Agreements (MTA)

    The IRB C2 will forward the project to an IRB Committee member or members to serve as the designated reviewer. The IRB C2 selects whether to forward the item for Exempt review or Expedited review based on their analysis of the project.
    - If the designated reviewer believes that the project does not qualify for review via the assigned pathway, they should discuss with the IRB C2.

3. The designated reviewer will use the applicable IRB review checklist (Exempt, Expedited, or Full Committee for items that qualify as minimal risk but are reviewed at a convened meeting) to evaluate the submission and additional documents, to ensure that:
    a. For projects which qualify as Exempt:
        - Principles of respect for persons, beneficence, and justice are appropriately addressed.
        - If there are interactions with subjects, there will be an appropriate consent process.
        - Apply & document the requirements of limited review when required.
    b. For projects which qualify for expedited review:
        - The criteria for approval have been met per the federal regulations (45 CFR 46.111 and/or 21 CFR 56.111).
        - Review the consent process and/or if a waiver or alteration of consent may be granted.
        - Designate the length of IRB approval

4. The designated reviewer will send back any modification requests via eBridge to the IRB C2 to return to the project team.
    a. This action can be repeated if, after the project team responds to these requests, outstanding questions remain.

5. Once all the designated reviewer requests have been satisfactorily addressed by the project team and the Reviewer confirms that the project qualifies as Exempt or Expedited, the Reviewer will “Approve” the item in eBridge and upload the completed IRB review checklist.

Review of Amendments:

1. When reviewing changes to the project via an Amendment, the review process is similar as the initial New Protocol Review. The IRB C2 forwards the eBridge AME SmartForm submission to the designated reviewer, and modifications should be requested and satisfied as needed prior to approval.
2. If changes proposed in eBridge AME submission, no longer fit the review categories under which the project was previously approved, the designated reviewer must consider whether a different level of review is needed.
    a. Examples include Projects reviewed under Expedited category 2 may add an activity that also requires review under Expedited category 4, or a project previously approved as Expedited may need to be reviewed at a convened meeting due to the addition of a Not Significant Risk device.
        i. The Reviewer should note any changes in category or review pathway in their determination checklist.
3. If the designated reviewer identifies that the project no longer appears to qualify as minimal risk, the designated reviewer should contact the IRB Chair and/or C2 to discuss further action and recommend review by the Convened Full Committee.

Review of Continuing Progress Reports (CPR):

1. Research which was determined to qualify for expedited review per the federal regulations will submit either a CPR or a 6-Year Renewal.
2. When a CPR or 6-Year Renewal, the review process is like the initial New Protocol Review. The IRB C2 forwards the eBridge CPR SmartForm submission to the designated reviewer, and modifications should be requested and satisfied as needed prior to approval.
3. During the review of either CPR or 6-Year Renewal, the designated reviewer should reconfirm the initial approval categories and any changes since initial approval still continue to qualify as minimal risk and under the identified categories.
    a. If that the identified review categories under which the project was previously approved do not appear accurate, the designated reviewer should include in the IRB review checklist for inclusion in the CPR approval letter.
    b. If the project does not appear to qualify as minimal risk, the designated reviewer should contact the IRB Chair and/or C2 to discuss further action and recommend review by the Convened Full Committee.
4. The designated reviewer will send back any modification requests via eBridge to the IRB C2 to return to the project team.
    a. This action can be repeated if, after the project team responds to these requests, outstanding questions remain.
5. Once all the designated reviewer requests have been satisfactorily addressed by the project team and the Reviewer confirms that the project qualifies as Expedited, identify an appropriate length of IRB approval.
6. The Reviewer will “Approve” the item in eBridge and upload the completed IRB review checklist.

REFERENCES:

45 CFR 46.102
45 CFR 46.104
45 CFR 46.110
21 CFR 56.102
21 CFR 56.104

21 CFR 56.110
Food and Drug Administration sections 505(i) and 520(g)

SUPPORTING DOCUMENTS:

MCW Corporate Policy: Human Research Protection Program (RS.HS.040)
MCW Corporate Policy: Research involving Human Subjects and/or their Private Identifiable Information (RS.HS.010)
IRB Member Form: Exempt Reviewer Checklist
IRB Member Form: Expedited Protocol Approval Checklist

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