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:
As outlined in the *MCW Corporate: Human Research Protection Program (RS.HS.040),* the MCW HRPP Office is charged with reviewing all research governed by the 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 HRPP Office is authorized to make the following determinations for research involving humans.

1. The HRPP Office will determine whether or not 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.
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 the investigator.

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.

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 or not 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. 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.

    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. 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 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 provided that they meet conditions detailed in 45 CFR

46.104. FDA regulations define very limited exemptions from the IRB requirement 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 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 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. The Investigator will complete and submit the initial eBridge SmartForm for the IRB to review. The "Research Project" 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. Project protocol
    b. Consent Form(s) or a Consent Script (if applicable)
    c. Recruitment materials (if provided)
    d. Data Collection Sheets (if applicable)
    e. Any grant application or contract
    f. Questionnaires or surveys

    The C2 will forward the project to an IRB Committee member or members to serve as the Reviewer. The C2 selects whether to forward the item for Exempt review or Expedited review based on their analysis of the project; however, if the Reviewer believes that the project does not qualify for review via the assigned pathway, they should discuss with the C2.
3. The Reviewer will use the accordant Reviewer checklist (Exempt, Expedited, or, 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. The activity qualifies as Exempt or Expedited research, and under which categories. All research activities must meet established minimal risk research categories in order for the project as a whole to be approved as a minimal risk project.
    b. Principles of respect for persons, beneficence, and justice are appropriately addressed.
    c. If there are interactions with subjects, there will be an appropriate consent process.
4. The Reviewer will send back any modification requests via eBridge to the C2 to return to the project team. This action can be repeated if, after the project team responds to these requests, outstanding questions still remain.
5. Once all 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 Reviewer checklist.

Review of Amendments and Continuing Progress Reports:
1. When reviewing changes to the project or if a continuing progress report is required, the Review process is similar. The C2 forwards the item to the Reviewer, and modifications should be requested and satisfied as needed prior to approval.

2. If changes proposed by the project team via Amendment do not fit the review category(ies) under which the project was previously approved, the Reviewer must consider whether a different level of review is needed. For example, a project 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. The Reviewer should note any changes in category or review pathway in their determination checklist.
    a. If the project no longer appears to qualify as minimal risk, the Reviewer should contact the Chair and/or C2 to discuss further action.
3. During the review of a Continuing Progress Report for qualifying Expedited projects, the Reviewer should reconfirm the approval categories.
    a. If the Reviewer notes that the review category(ies) under which the project was previously approved do not appear accurate, this should be included in the Reviewer checklist for inclusion in the Contiuing Progress Report approval letter.
    b. If is is identified during this review that the project does not appear to qualify as Expedited, the Reviewer should contact the Chair and/or C2 to discuss further action.

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: Human Research Protection Program (RS.HS.040)
IRB Member Form: Exempt Reviewer Checklist
IRB Member Form: Expedited Protocol Approval Checklist

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