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):**

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.
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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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