MCW Office of Research
Standard Operating Procedure

LAPSED IRB APPROVALOF HUMAN SUBJECT RESEARCH

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

Applies to: Faculty and Staff involved in human research

PURPOSE:
The IRB is required to conduct continuing review of research approved under federal regulations at intervals appropriate to the degree of risk. Principal Investigators (PI) who fail to submit a progress report or provide additional information concerning a submitted progress report delay the IRB's continuing review of research and fail to comply with one of the PI's primary responsibilities under federal regulation and MCW IRB policies

DEFINITIONS:
N/A

POLICY:
Investigators must submit and obtain approval for a Continuing Progress Report (CPR) or submit a Final Progress Report to the IRB prior to expiration of IRB approval for the research project.

If an Investigator fails to submit and obtain approval for a CPR or submit a Final Progress Report prior to the expiration of the research project's IRB approval; the IRB will not accept any new human subject research applications from the PI until approval has been obtained for the CPR or a Final Progress Report has been submitted/accepted for any expired projects.

The IRB will not accept an amendment to change the PI of a project if the proposed PI has any research projects with expired IRB approval.

PROCEDURE:
1. Investigators who do not submit and obtain approval for a CPR or submit a Final Progress Report prior to the expiration of the research project's IRB approval will receive an IRB Expiration Letter.
    a. This letter will be issued via the eBridge system
2. Upon receipt of the IRB Expiration Letter, the PI must:
    a. Submit a CPR or a Final Progress Report to the IRB for review within 14 calendar days, if a CPR or Final Progress report was not submitted for this reporting period.
    b. Submit the requested information in response to the IRB's request regarding the CPR/Final Progress report within 5 calendar days, if a CPR or Final Progress Report was submitted to the IRB.
    c. Provide an explanation for the lapse IRB Approval and a Corrective Action Plan to prevent any repetitions.

    d. Inform the IRB if there are enrolled research subjects who need to continue participation in research activities during the lapsed IRB approval.
    e. Petition the IRB to continue specific project activities if they are in the subject's best interest.
3. If there is no response to the IRB Expiration Letter the PI will receive a second notification Continuing Expired IRB Approval from the HRPP Director. This second notification remind the PI of the following:
    a. All research activities must stop until IRB approval has been obtained
    b. To submit of a CPR or a Final Progress Report to the IRB
    c. Respond to the IRB's requests for additional information and/or modification to an already submitted CPR or Final Progress Report
    d. Provide an explanation for the lapsed IRB approval and a Corrective Action Plan to prevent any repetitions.
    e. The following individuals are copied on the emailed notification:
        i. IRB Managers
        ii. IRB Operations Managers
        iii. The PI's Department Chair – or – Division Chief
        iv. The Committee specific IRB Coordinator II
4. The "Continuing Expired IRB Approval" notification is available in the project's eBridge workspace history.
5. Projects that remain expired after the PI's receipt of the IRB Expiration Letter and the Continuing Expired IRB Approval notification will be tracked for further follow up by the HRPP Director with the PI's Department Chair and/or Division Chief and if applicable, the PIs, requesting resolution.

REFERENCES:
N/A

SUPPORTING DOCUMENTS:
N/A

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Approved By
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