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 HHS and/or FDA regulations at intervals appropriate to the degree of risk but not less than once a year. 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:
Principal 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. Upon receipt of the eBridge Expiration Letter informing the PI that the IRB approval has expired for the research project, the PI must:
    a. Submit a CPR or a Final Progress Report to the IRB for review within 14 calendar days, if no CPR or Final Progress report was submitted for this reporting period.
    b. Submit information in response to the IRB's request regarding the CPR/Final Progress report within 5 calendar days.
    c. Provide an explanation for the lapse IRB Approval and a Corrective Action Plan to prevent any repetitions.
    d. Inform the IRB if it is in the enrolled research subjects best interest 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.
2. If there is no response to the eBridge Expiration Letter the PI will receive an email, Expired IRB Approval, from the HRPP Director requesting:
    a. Submission of a CPR or a Final Progress Report to the IRB

   b. Response regarding the IRB's requests for additional information and/or modification
   c. An explanation for the lapsed IRB approval and a Corrective Action Plan to prevent any repetitions.
   d. The following individuals are copied on the emailed notification:
      i. IRB Manager
      ii. IRB Operations Manager
      iii. The PI's Department Chair – or – Division Chief
      iv. The supporting IRB Coordinator I and II
3. A copy of the "Expired IRB Approval" notification is uploaded in the research project's IRB file.
4. Projects that remain expired after the PI's receipt of the eBridge Expiration Letter and the HRPP Director's Expired IRB Approval notification will be tracked for further follow up by the HRPP Director with the PI's Department Chair/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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