

- 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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