Obtain Approval BEFORE Starting Research

Principal investigators (PI) are responsible for obtaining Institutional Review Board (IRB) approval before beginning any human subjects research. When you submit a protocol to the IRB for review as the PI, you agree to comply with federal regulations and University policies and procedures for the study duration.

Continuing Review

- During its review, the IRB may require that a nonexempt research protocol submit continuing reviews (CR) at determined intervals.
- PIs must submit CR reports to the IRB, as long as they interact and intervene with human subjects for research purposes, or obtain and analyze identifiable private information as described in the IRB-approved research plan.
- PIs must submit their CR six (6) weeks before the expiration date report to the IRB for review.

  The HRPO at UMB sends out courtesy reminders via CICERO to investigators to submit their CRs.

  When a PI begins drafting a CR report, these reminders stop.

  When a PI does not submit their CR six (6) weeks before the expiration date, their application may be at risk of a lapse in IRB approval.

University of Maryland Baltimore

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PRINCIPAL INVESTIGATOR RESPONSIBILITIES: PREVENTION OF PROTOCOL EXPIRATION

University of Maryland Baltimore

HUMAN RESEARCH PROTECTIONS OFFICE (HRPO)

Expiration of IRB Approval

- The IRB approval expiration date is the first date that a protocol no longer has IRB authorization to conduct research activities.
- There is no grace period after the expiration date.
- A lapse in IRB approval means that the study is no longer active.
- All study activities must stop until the PI obtains IRB approval to resume activities.

Consequences of Expired Protocols

- The investigator is in noncompliance with federal regulations, and all study activities must cease.
- For federally funded or Food and Drug Administration (FDA)-regulated protocols, the applicable funding agency or FDA may require the IRB to notify them of lapses in approval.
- First lapse of approval:
  - The PI will receive a warning that they are noncompliant with federal regulations and University policy.
  - The PI must meet with the IRB Chair and the Assistant Vice President of Research Compliance.
- Repeated lapses or failure to maintain IRB approval across studies:
  - The PI must meet with the IRB Chair, the Assistant Vice President for Research Compliance, and the Institutional Official.
  - Due to the continuous noncompliance with regulations and policy, the institution may impose sanctions on the investigator.

Actions to Take If IRB Approval Expires

- First, contact the HRPO if you have questions on what you need to do if your study expires.
- Immediately submit a CR report if you have not done so. This needs to be done as soon as possible, but no later than five days from the time of expiration.
- Next, when you submit the CR report, you must also submit a reportable new information (RNI) report.
- In the RNI report you must:
  - Acknowledge that the incident is an instance of noncompliance with the regulations, requirements, and determinations of the IRB.
  - Provide the reasons for the lapse in approval.
  - Inform the IRB of any research activity that occurred after expiration.
  - Provide confirmation that all research activities have ceased as of the expiration date of the protocol.
  - Provide any corrective actions that the investigator is taking to prevent any such lapse of approval of the project from occurring again.

Participant Health and Safety

- When IRB approval expires, the investigator must stop all research activities.
- If stopping certain research activities until the protocol obtains its IRB approval could reasonably jeopardize the health or safety of a participant:
  - The study investigator must promptly notify the IRB to determine if continuing specific interventions is in the best interest of the participants receiving such interventions.
  - The IRB will review and notify the PI about whether they may continue specific interventions or interactions.

Continuation of Study After Expiration

Investigators may resume the human subjects research activity after the IRB completes its review of the CR and RNI reports and grants IRB approval for the research study to continue.

Study Completion

- The PI must report all studies' completion by submitting a closure report to the IRB before the IRB approval expiration date.
- UMB requires PIs to notify the IRB promptly after completing all research activities.
- Failure to close a study before the IRB approval expiration date will result in an expired protocol and noncompliance with the institutional requirements.