	IRB SOP: Lapsed/Expired IRB Approval of Human Subjects Research		
	NUMBER	APPROVED BY	EFFECTIVE DATE
	HSR-550	Miranda van Tilburg, PhD IRB Chair, IRB Office Campbell University	08/27/2021

Applies to Campbell faculty, faculty advisors, students and staff conducting or overseeing human subjects research.

Purpose

This procedure establishes the process for a Principal Investigator (PI) to submit a continuing review of an IRB Approved protocol or a progress report for minimal risk protocols, after the IRB Approval date has expired. The IRB is required to conduct continuing review of research approved under HHS regulations at intervals appropriate to the degree of risk but not less than once a year.

Background

The IRB is required to conduct continuing review of research approved under HHS regulations at intervals appropriate to the degree of risk but not less than once a year. If an Principal Investigator fails to submit and obtain approval for a Continuing Review (CR), Progress Report (PR) or submit a Closure Submission prior to the expiration of the research project's IRB approval expiration date; the IRB will not accept any new human subject research applications from the PI until approval has been obtained for the CR, PR or a Closure Submission for the Principal Investigator's expired protocol(s). The IRB will not accept an amendment to change the Principal Investigator of a project if the proposed new Principal Investigator has any research projects with expired IRB approval.

Definitions


None

Principal Investigator Responsibilities

Principal Investigators (PIs) must submit and obtain approval for a Continuing Review (CR), Progress Report (PR) or submit a Closure Submission to the IRB prior to expiration of IRB approval for the research project.

Procedures

1. Upon receipt of the Expiration Email informing the PI that the IRB approval has expired for the research project, the PI must:
 - a. Submit a CR, PR or a Closure Submission to the IRB for review within 30-45 calendar days depending on the type of submission, if no CR, PR or Closure Submission was submitted for this reporting period;
 - b. If the IRB requests information regarding the CR/PR/Closure, submit information in response to the IRB's query within 5 calendar days;
 - c. Response should include an explanation for the lapse IRB Approval and a Corrective Action Plan to prevent any repetitions;

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- 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 Expiration Email, by the expiration date of the protocol, the PI will receive an Expired IRB Approval Email, signed by the IRB Chair requesting:
 - a. Submission of a CR, PR or a Closure Submission to the IRB;
 - b. If the IRB requests information regarding the CR/PR/Closure submit information in response to the IRB's query within 5 calendar days;
 - c. Response should include an explanation for the lapse IRB Approval and a Corrective Action Plan to prevent any repetitions; 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 from the IRB Chair:
 - i. Dean of the School;
 - ii. Department Chair.
3. A copy of the "Expired IRB Approval" notification is uploaded in the research project's IRB protocol record.
4. Projects that remain expired after the PI's receipt of the Expiration Letter and the IRB Chair's Expired IRB Approval notification email are in non-compliance status.
5. If the protocol remains in a non-compliance status for 14 days following its expiration date, the Investigator will be placed on the Restricted Investigator Log and remain there until the appropriate submission and corrective action plan has been received. Investigators on the Restricted Investigator Log will only be allowed to submit Reportable Events.

The PI, the PI's Department Chair and/or School's Dean will receive an email, "Restricted Investigator Notification", from the IRB Chair.

References

45 CFR 46.104(d)(2)(iii), (d)(3)(i)(c), and (d)(7) and (8);
 45 CFR 46.109(e)(f)