CAMPBELL UNIVERSITY	**IRB SOP:** Continuing Review and Progress Reporting of IRB Approved Protocols		
	NUMBER	APPROVED BY	EFFECTIVE DATE
	HSR-540	Miranda van Tilburg, PhD IRB Chair, IRB Office Campbell University	12/02/2020

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

Purpose

This procedure establishes the process for Principal Investigators to submit a continuing review or progress report to an IRB Approved protocol for approval by the IRB prior to the expiration date of the IRB approved protocol. The procedure also explains the criteria for research that does not require continuing review.

Background

In accordance with Federal regulations and institutional policy a continuing review (CR) must be submitted for review and approval at intervals appropriate to the degree of risk, but not less than once per year unless at the time of the initial review the IRB determined that the approved protocol did not meet the criteria for continuing review. Factors for making the decision about the frequency of review include the level of risk, location of the project, and any other factors that might affect the welfare of the subjects. Frequency of review is determined by the IRB upon initial review. For protocols that the IRB has determined do not meet the criteria for continuing review a progress report (PR) must be submitted to revise the project's end date.

Definitions

None

Principal Investigator Responsibilities

It is the Principal Investigator's responsibility to ensure that a CR or PR is completed and submitted to allow the IRB adequate time to conduct continuing review of the project before the expiration date. While the IRB office will issue email reminders to remind the Principal Investigator (PI) of the approaching CR or PR deadline, the PI bears the ultimate responsibility for knowing the expiration date issued when the project received approval. The deadline for submission of CRs to the IRB is 45 business days prior to the project expiration date. If a renewal approval is not obtained before the end of the previous IRB approval expiration date, all research activities need to be stopped after that date, until renewal approval is obtained. A project that does not receive renewal before the expiration date may be administratively close and cannot be re-opened. See *IRB SOP: Lapse/Expired IRB Approval of Human Subjects Research* for more information.

Procedure

Continued approval must be requested as follows:

- **Exempt, Registration Project (by FLEX review) and Expedited** *(without continuing review requirement)* – Protocols previously determined/approved by exempt, registration project by FLEX review and expedited without continuing review requirement, must submit a *Progress Report Submission Form* and a revised project end date will need to be provided. The IRB will review the protocol to verify the project's progress and determine that the protocol continues to qualify for exemption or registration or expedited without continuing review. A revised expiration date will be issued.

- **Expedited and Full Review** – Projects previously determined to require expedited with continuing review or full review, must submit a *Continuing Review Submission Form*. The IRB must conduct a continuing review of the protocol annually, at minimum, and determine that all the approved criteria specified in the federal regulations continue to be satisfied. If approved, the IRB will issue continued approval with a new expiration date.

IRB Review

1. CRs must be submitted using the *Continuing Review Submission Form* found on the IRB website, along with other supporting documents. Submit the form using the *Continuing Review Electronic Application Form*.
2. PRs must be submitted using the *Progress Report Submission Form* found on the IRB website, along with other supporting documents. Submit the form using the *Continuing Review Electronic Application Form*.
3. Federal regulations require that continuing review of research be substantive and meaningful.
4. During the continuing review, the IRB will determine if the research project continues to meet all criteria set forth by federal regulations in order for the IRB to approve research. In order for the IRB to comply with these regulations, the Investigator must provide complete information in the CR/PR submission, including:
    a. the number of subjects accrued/enrolled to the project since the last IRB review
    b. the number of subjects withdrawn from the project since the last IRB review and a summary of the reasons for withdrawal
    c. a summary of any complaints about the project since the last IRB review and a summary of any recent literature that may be relevant to the project
    d. any previous amendments or modifications to the project since the last IRB review and any relevant multi-center project reports.
    e. If the Investigator is the lead PI of a multi-site project, additional information is required as described in the *IRB SOP: Conducting Multi-site (sIRB) Research and Investigator Responsibilities*.
    f. a summary of available information regarding any internal and external (if applicable) unanticipated problems and adverse events

g. any other relevant information, especially information about risks associated with the project
h. a copy of the current IRB approved informed consent document(s), if applicable.

Any changes to the consent form or to the project must be submitted using an amendment prior to the Continuing Review (CR) or Progress Report (PR). See *IRB SOP: Amendment to Approved IRB Protocols* for more information.

Suspension or Termination at the Time of Continuing Review: Suspension or termination of a project may occur at any point throughout the life of a project, including at the time of continuing review.

Lapse of IRB Approval

1. If an PI does not provide a CR or PR to the IRB prior to the expiration date or with enough time to review the CR or PR prior to the expiration date; OR
2. If the IRB approves the CR with modifications and these are not reviewed and approved prior to the expiration date:
    a. All research activities must stop.
    b. Interventions and interactions on current subjects must stop, unless the IRB finds an over-riding safety concern or ethical issue involved such that it is in the best interests of individual subjects to continue participating.
    c. New enrollment of subjects is not allowed to occur.
3. Any research activity on an expired or suspended project would constitute unapproved human research and, is considered serious noncompliance with CU policies and procedures regarding the conduct of human subject research. This finding would be reported by the IRB Committee to the Campbell University Institutional Official, and applicable federal agencies, if required.
4. The IRB Office should be contacted immediately if it is in the best interest of accrued/enrolled subjects to continue treatment or to continue being evaluated so they can safely complete the project. The Investigator may no longer use further data about the subjects for research purposes.
5. If the PI wishes to reactivate the project, he/she should submit a Continuing Review Submission Form, Progress Report or contact the IRB regarding the status of their currently submitted CR or PR. If the Investigator does not submit a CR for the project within 45 days of expiration, the IRB will require the Investigator to submit a new project submission. Please see *IRB SOP: Lapsed/Expired IRB Approval of Human Subjects Research* for further information.

Research that Does Not Require Continuing Review (CR)

Research meeting the following requirements does not require continuing review unless otherwise determined by the IRB:

- Research eligible for expedited review under 45 CFR 46.110;

- Research reviewed by exempt-limited IRB review;
- Research determined to be exempt;
- Research determined to be a Registration Project by FLEX review;
- Research that involves only one or both of the following in accordance with the IRB-approved project:
    - Data analysis, including analysis of identifiable private information or biospecimens;
    - Accessing follow-up clinical data from procedures that are part of routine care.

If the IRB determines that continuing review (CR) is required even though a project meets the above conditions, the reviewer will document the rationale for conducting continuing review on the appropriate reviewer checklist at the time of the initial IRB review and it will be in the IRB approval letter for the protocol. If the CR required convened committee review, the rationale will also be recorded in the minutes.

References

45 CFR 46.104(d)(2)(iii), (d)(3)(i)(c), and (d)(7) and (8);
45 CFR 46.109(e)(f)
45 CFR 46.110(b)(3)
IRB SOP: Amendment to Approved IRB Protocols
IRB SOP: Conducting Multi-site (sIRB) Research and Investigator Responsibilities
IRB SOP: Lapse/Expired IRB Approval of Human Subjects Research