CAMPBELL UNIVERSITY	**IRB SOP:** Amendment to Approved IRB Protocol		
	NUMBER	APPROVED BY	EFFECTIVE DATE
	HSR-530	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 modification(s) or change(s) to an IRB Approved protocol for review and approval by the IRB prior to initiation of the modified or changed research activities.

Background

Principal Investigators who wish to change or modify an ongoing IRB-approved project must submit an amendment to the IRB and receive IRB approval before implementing any modification. These changes must be submitted to and approved by the IRB prior to implementation. Exceptions to this process are described in this procedure.

EXCEPTIONS

1. A modification that is necessary to eliminate apparent immediate hazards to the research participant [45 CFR 46.108(a)(3)(iii)]. In such a case, the modification can be implemented before IRB approval. The modification must be promptly (no longer than 30 days) reported to the IRB via a reportable event, and the IRB will review the change to determine that it is consistent with ensuring the research subjects' continued welfare.
2. Updates such as changes to non-key personnel (administrative staff or staff that does not conduct research activities) or contact information should be filed with the IRB by sending an email to the IRB Coordinator prior to initiating the changes.

Definitions

None

Principal Investigator Responsibilities

1. Amendments must be reviewed and approved prior to incorporating the proposed change(s) into the project. When a Principal Investigator (PI) receives an amendment or a request for change to the approved project from a sponsor or agency, they must submit the amendment promptly to secure final IRB approval within 90 days from notification of the change. In addition, PIs and project teams should work to respond quickly to any requested modifications to meet this expectation. This timeframe ensures the changes can be implemented in a timely process to protect the rights, safety, and welfare of their subjects and that the continued conduct of the project is carried out in accordance with the protocol.
2. Examples of changes that need review by the IRB include but are not limited to:
    a. Change in PI

i. This change requires the new PI to complete and sign the *IRB Investigator Agreement* and upload this document into the *Amendment (AME) Electronic Application form*.

b. Addition of research staff
c. Increase or decrease of enrollment numbers
d. Change in recruitment methods or materials
e. Change in the consent form
f. Change to an Investigator Brochure or device information
g. Change in inclusion/exclusion criteria
h. Change in procedures
i. Adding or dropping an arm of the project
j. Change to questionnaires, surveys, interview scripts
k. Change in funding
l. Change in the title of the project
m. Addition of new project sites or locations which will be under the direction of the PI. For more information, see *IRB SOP: Reliance Agreements for Multi-Site Projects*.
n. Revised *Research Plan*

3. PIs must describe the changes proposed to the approved project in the *Amendment (AME) Submission Form*. The Investigator should include in the description where the changes are cited in the revised *Research Plan*, any change to the consent form (if applicable), or revisions to other project-related documents including but not limited to protocol summaries, data collection forms, surveys, or questionnaires. In addition, Investigators must provide the rationale for the changes to the project.

Procedures

Use the *Amendment Electronic Application Form* for the following:

Amendment (AME) Submission Form (found on the CU IRB website) which includes:

- Instructions
- Protocol Information
- Proposed Changes
- Research Personnel
- Research Risk
- Collaborations
- Clinical Trials Information
- Materials
- Revised *Research Plan.*
- Other applicable documents

Other Federal Agencies Requirements:

1. For projects that receive funding from a federal agency or may be subject to additional federal agency specific requirements, the following must be applied and considered during the review process:
    a. **Department of Defense:** All substantive amendments to approved research must undergo scientific review prior to IRB review.
        i. The USAMRMC HRPO defines a substantive modification as a change in PI, change or addition of an institution, elimination or alteration of the consent process, change to the project population that has regulatory implications (e.g., adding children, adding active duty population, etc.), significant change in project design (i.e., would prompt additional scientific review), or a change that could potentially increase risks to subjects.
        ii. Documentation of this scientific review must be included with the amendment documents or indication from the funding agency if this was not required.

Some amendments may require review by various administrative or ancillary committees prior to being reviewed by the IRB. Investigators should be aware of these processes when planning to submit an amendment to the IRB.

IRB Review of Amendment

1. When an amendment is received by the IRB, the IRB office will review the amendment and attached documents for completeness and determine the type of IRB review the project activities qualify for based upon the risks and proposed changes involved. The IRB reviews amendments under the following categories:
    a. FLEX Review for Registration Projects
    b. Exempt Review
    c. Exempt-Limited Review as a condition
    d. Expedited Review
    e. Convened Committee Review.

    Depending on requested changes in the amendment, the category for IRB approval may change upon (pre)review.
2. The IRB will notify PIs of its decision to approve or disapprove the proposed changes to the project as well as any modifications required to secure IRB approval. If the IRB decides to disapprove a modification, it will include in its written notification a statement of the reasons for its decision.
3. If the amendment meets criteria for convened committee review, the PI and project staff are notified of the disposition of the amendment within 5 business days following an IRB Committee meeting.
4. If the amendment meets criteria for non-committee review, the PI and project staff are notified of the disposition of the amendment within 5 business days of the approval.

5. The IRB Coordinator should be contacted for questions related to the amendment.

References

45 CFR 46.108(a)(3)(ii)