CAMPBELL UNIVERSITY	**IRB SOP:** Institutional Review Board Determination or Approval		
	NUMBER	APPROVED BY	EFFECTIVE DATE
	HSR-570	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 describes the authority of the Campbell University Institutional Review Board (IRB) or the designated reviewer to render determinations or approvals according to the Federal Regulations and to place restrictions on a research project or suspend or terminate approval of a research project that is not being conducted in accordance with institutional procedures or applicable law, or that has been associated with unexpected harm to subjects.

Background

The IRB reviews research in accordance with the applicable institutional and regulatory criteria for determination and approval.

Definitions

N/A

Responsibilities

The Campbell IRB is responsible for conducting reviews and to approve, require modifications (to secure approval), disapprove, suspend or terminate human research activities conducted at Campbell University.

Procedures

1. Prior to Review

Determination of review type – Applicants will submit their suggested type of review.

In order to determine the type of review necessary, the IRB staff screens the entire application and makes determinations as to whether the project constitutes human subjects research and, if so, the type of review required. All applications are assigned to be reviewed at a convened meeting unless:

a) The protocol meets the criteria for expedited review; or
b) The protocol meets the criteria for exemption;
c) The protocol meets the criteria for registration project by FLEX review;
d) The protocol meets the criteria for non-human subject research (NHSR) as explained on below.

For all applications assigned to be reviewed at a convened meeting, all decisions require a simple majority vote. See *IRB Actions following review by the convened IRB* below for further description.

2. Review by Convened IRB

Scheduling of Meetings

The IRB sets its own meeting schedule, but generally the IRB should meet at least once a month on a regularly scheduled day with the exact frequency to be determined by workload.

Scheduled meetings may be cancelled by the chair due to a) insufficient number of applications requiring review at a convened meeting, b) inability to secure a quorum for attendance, or c) other reasons as may arise that make a scheduled meeting unnecessary or otherwise inappropriate. At Campbell University the IRB does not meet in June, July and August.

The Chair will notify members of meetings.

Recusal of members with a conflict of interest

When an IRB member has a conflict of interest that requires him/her to recuse himself/herself from discussion of and voting on a particular protocol, that member should leave the meeting room for the duration of the discussion and vote, except as requested to address questions raised by other members. If the member's recusal causes a loss of quorum, the vote should be postponed to another meeting. For this reason, IRB members should notify the chair prior to the meeting if they have a conflict of interest related to a specific protocol slated for review at the meeting, and every effort should be made to ensure adequate members in attendance.

3. IRB Actions following review

Approved

Approval may be granted if the research activity meets the criteria for approval as defined in 45 CFR 46.111 or 21 CFR 56.111 and no changes to the research application are recommended. Research may proceed once the Principal Investigator (PI) receives written documentation of IRB approval.

Modifications Required/Conditional Approval

A "modifications required" status is stipulated only when the requested modifications are clear and specific in nature and do not require clarification by the PI. Clarifications that are minor and will not change the risk to the subject regardless of the response can also be given a "modifications required" status. Modifications will be reviewed by the IRB Chair or designated IRB member. Those that are not addressed by the Investigator and/or project team may be referred to the Full Board, as determined by the IRB Chair or Board. The recommended modifications must be made to the IRB submission, Sponsor's protocol, informed consent documents, and/or other required documents before final IRB approval

can be granted. The date of approval is the date the conditions were determined to be met. The IRB Board provides a letter to the Investigator stipulating the specific modifications required for approval.

1. Initial submissions receiving a "modifications required" status will be administratively withdrawn if an adequate response to the Board recommendations has not been received by the IRB within 60 days of the date of the "modifications required" letter.
2. Continuing review submissions receiving a "modifications required" status will expire on the date of project expiration if required modifications have not been received and approved by the IRB prior to the project expiration date.
3. Amendments receiving a "modifications required" status may not be implemented until a response by the PI has been received and final approval has been granted in writing by the IRB. Some examples of minor changes are changes in contact information or identity of non-key research personnel, changes in the study title, and changes in the consent form that reflect the minor changes listed earlier.

For minor changes, the IRB Chair or IRB Staff must ensure that the PI makes the appropriate changes to the research protocol. The research may proceed after the required changes are verified and the designated reviewer approves the protocol.

A "conditional approval" status is only stipulated when the investigator is required to submit required documents and the IRB does not need to judge whether these documents meet the regulatory criteria for approval. The research may proceed after the documents have been reviewed by the IRB Chair or IRB Staff. For example, these documents may be letters of support from participating sites, such as clinics or schools at which subjects will be recruited.

Deferred

A project may be "deferred" when the Board lacks sufficient time, at a full Board meeting, to review a submission. The submission is placed on the next IRB Full Board meeting agenda. A project may also be "deferred" if the primary reviewer and/or consultant or subject matter expert is unable to provide or complete their review of the submission and provide documentation of this review prior to the convened IRB Full Board meeting.

Tabled

A "tabled" status is stipulated when the project does not meet the criteria for approval as defined in 45 CFR 46.111 or 21 CFR 56.111, if the IRB Board requests substantive modifications to the IRB submission that are relevant to the determinations required by the IRB. A project that lacks sufficient information to conduct an adequate review at the Full Board review level is "tabled" pending receipt of the requested information. The revised project must be reviewed by the convened IRB and is placed on the next available agenda pending receipt of the additional information. The Investigator's response is reviewed by the Full Board.

1. The IRB Board may invite the PI to a convened IRB Board meeting to allow the Investigator to personally address the concerns of the Board and to allow the Board to ask questions and seek clarification from the PI.
2. Initial submissions receiving a “tabled” status are administratively withdrawn if a response to the Board modifications has not been received by the IRB within 60 days of the date of the tabled letter.
3. Continuing review submissions receiving a “tabled” status expire on the date of project expiration if an adequate response has not been received by the IRB prior to the project expiration date.
4. Amendments receiving a “tabled” status may not be implemented until a satisfactory response by the Investigator has been received and final approval has been granted in writing by the IRB.

Disapproval

A “disapproved” status is stipulated when the project does not meet the criteria for approval as defined in 45 CFR 46.111 or 21 CFR 56.111, and if the IRB Board recognizes the project puts subjects at substantial risk, or presents a significantly unfavorable risk-benefit ratio and cannot recommend substantial revisions to the IRB submission, Sponsor’s Protocol, informed consent document(s), and/or other pertinent documents outside of not conducting the project as presented.

Suspension and termination

A “suspended” status is a temporary halt in IRB approval of some or all research activities until identified concerns can be evaluated and resolved. Suspension may be initiated whenever:

- it is determined that research is not being conducted in accordance with IRB requirements and approval based on outcome from an inquiry or investigation, or
- when significant new risks are identified and need to be evaluated, or
- unexpected serious harm to subjects has occurred.

Though the chair may suspend the study, only the convened IRB can make the decision to terminate a study. A “terminated” status is a permanent halt in IRB approval for all research activities. Termination is initiated when it is determined, through investigation, that research is not being conducted in accordance with IRB requirements in which the reported risks significantly outweigh the benefits, or unexpected serious harm to subjects has occurred.

The IRB may terminate a project without "Suspending" project activities previously.

Notification of IRB Decision

The IRB sends written notification of actions taken to the PI. If revisions to new and continuing human subjects' applications are required, correspondence is sent to the investigator detailing requests for revisions, clarification, or additional information as well as information regarding continuing review.

FLEX Review and Expedited Review of Submissions

The same procedures as described will apply to studies that meet criteria for FLEX review (Registration Projects) and Expedited review. The actions will either be performed by a single designated reviewer or may be performed by a convened Full Committee; if a submission is deemed to warrant review by a convened Full Committee as determined by the IRB Chair.

References

45 CFR 103(e); 45 CFR 46.104(d)(2)(iii), (d)(3)(i)(c), and (d)(7) and (8);
45 CFR 46.108(3), (4)
45 CFR 46.109
45 CFR 46.110
45 CFR 46.111
HRPP Policy: Registration Projects and FLEX Review