CAMPBELL UNIVERSITY	**IRB SOP:** Closure of IRB Approved Protocol		
	NUMBER	APPROVED BY	EFFECTIVE DATE
	HSR-560	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 (PIs) to submit a closure of an IRB Approved protocol after termination, completion of a research project or the Investigator's part of the research project has been completed.

Background

The CU IRB requires that an Approved IRB protocol be closed when the project is completed or terminated. A project may be considered completed when the following project activities are finished, or they are no longer occurring and have been halted:

- Screening and recruiting of new participants
- Enrolling participants into project
- Treatment of enrolled participants
- Follow up on enrolled participants
- Data collection has ceased
- Submitting of amendments
- Submitting Continuing Review
- Filing of SAE's
- Filing of Protocol Deviations

Definitions

None

Principal Investigator Responsibilities

1. The Principal Investigator (PI) must file a *Closure Submission Form* to close a project when:
    a. all project activities are completed as designed; or
    b. the PI determines the research will not be able to be completed as approved by the IRB;
    c. The project is terminated by the Sponsor or other party for any reason.

2. A subset of projects may submit a *Closure Submission Form* to the IRB if the only activity occurring within the project is data analysis. To qualify the project must meet the following criteria:
    a. Is not federally funded
    b. Is not regulated by FDA
    c. Does not have an Inter-Institutional Agreement (Reliance Agreement) deferring IRB review from another institution to Campbell University IRB.

Procedures

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

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

- Instructions
- Protocol Information
- Status
- Progress Report
- Clinical Trials Information

Human Subject Research Deferred to an External IRB

PIs of research projects which have been deferred by the Campbell IRB to an external IRB for oversight must notify the Campbell IRB Office when the project closes at this site.

Retention of Research Records

- At a minimum, Investigators must maintain project materials and records for at least three (3) years from the date the project is closed with the Campbell IRB, per Campbell University HRPP Policy.
- Requirements for record retention vary with the type of project conducted and provisions of the PI's funding source. It is the Investigator's responsibility to have a clear understanding of the retention requirements of a sponsor and/or the agency as applicable.
- All project records must be accessible for inspection and copying by authorized representatives of the institution, the IRB, federal regulatory agency representatives, and the department or agency supporting the project.
- The inventory and location of the stored research records should be on file with the Investigators department in the event the Investigator is no longer with Campbell University.

References

None