	IRB SOP: Requirements & Qualifications to Serve as a Principal Investigator (PI)		
	NUMBER	APPROVED BY	EFFECTIVE DATE
	HSR-310	Miranda van Tilburg, IRB Chair IRB Office Campbell University	12/02/2020

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

Purpose

To define and explain the requirements and qualifications of persons who assume the role of Principal Investigator (PI) of human research subject research project.

Background

Campbell IRB currently recognizes the following classes of individuals that are eligible to work as a Principal Investigator:

- Faculty
- Staff
- Residents and Fellows may serve as the PI on projects. They must include a Faculty Advisor. Given that residents/fellows are still learning, they are allowed to have the day to day responsibility for a research study. However, the faculty advisor will hold the final responsibility for the conduct of the project.

A PI has overall responsibility for the conduct of a research project, including all technical, programmatic, financial, compliance, and administrative aspects. The PI is responsible for controlling the technical direction and academic quality of the project, and will ensure that the project is carried out in compliance with the terms, conditions, and policies of the institution and sponsor, when applicable.

All PIs engaged in the conduct of human subject research under the oversight of Campbell IRB must complete required human subjects research protections training prior to submission of a research project for review and approval to the Campbell IRB. PIs are required to remain up-to-date with required trainings to continue to conduct research as outlined in the *IRB SOP: Human Subject Research Protections Training Requirements*.

Definitions


Human Subject: a living individual about whom an investigator (whether professional or student) conducting research obtains:

1. Data through intervention or interaction with the individual; or
2. Identifiable private information

Definition of Investigator:

For the purposes of the HHS regulations, Office for Human Research Protections (OHRP) defines investigator as any individual who is involved in conducting human subject research studies. Such involvement would include:

1. Obtaining information about living individuals by intervening or interacting with them for research purposes;

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2. Obtaining identifiable private information about living individuals for research purposes;
3. Obtaining the voluntary informed consent of individuals to be subjects in research; and
4. Studying, interpreting, or analyzing identifiable private information or data for research purposes.

Investigators can include physicians, scientists, nurses, administrative staff, teachers, and students, among others. Some research projects are conducted by more than one investigator, and usually one investigator is designated the “principal investigator” with overall responsibilities for the project. In every human subject research project, investigators have certain responsibilities regarding the ethical treatment of human subjects. (45 CFR 46)

The Food and Drug Administration (FDA) defines investigator as an individual who actually conducts a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject, or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team. (21 CFR 50.3 (d))

Definition of Principal Investigator

The CU IRB defines Principal Investigator (PI) as anyone who engages in the following:

Any individual who leads or directs a research project involving human subjects; this includes any individual who leads or directs projects that:

1. engage CU in anyone else’s research project outside of CU
2. uses CU resources; including lab equipment, physical space, or services;
3. brings research data onto the campus;
4. performs any research activity on CU campus
5. acts as the Faculty Advisor for a student research project.

A PI has overall responsibility for the conduct of a research project, including all technical, programmatic, financial, compliance, and administrative aspects. The PI is responsible for controlling the technical direction and academic quality of the project and will ensure that the project is carried out in compliance with the terms, conditions, and policies of the institution and sponsor, when applicable. Therefore, the Campbell IRB will only recognize the lead PI located at Campbell University.

References

45 CFR 46

21 CFR 50.3

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