CAMPBELL UNIVERSITY	**IRB SOP:** Conflict of Interest in Human Subjects Research		
	NUMBER	APPROVED BY	EFFECTIVE DATE
	HSR-311	Miranda van Tilburg, PhD, IRB Chair, IRB Office Campbell University	06/22/2020

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

Purpose

To describe the procedures for reporting and managing any significant financial or personal conflict of interest (COI) held by Campbell University investigators and project team members that could affect research involving human participants.

Background

Human research protocols must be reviewed for potential conflicts of interest involving possible financial gain or other personal advantage to persons, associated with the research. Investigators are required to disclose potential conflict of interest when conducting research managed or sponsored by the Public Health Service (PHS) and their components (i.e., National Health Institute (NIH)) and the National Science Foundation (NFS).

In instances where a conflict of interest involving human subject's research is allowed, it is essential that research subjects and other interested parties be informed of the conflict of interest. Notification of research participants fall within the purview of the applicable IRB, which will determine whether and how the conflict of interest should be disclosed to the human research participants. The IRB may require additional safeguards to mitigate actual or perceived conflictions of interest

Definitions

Conflict of Interest refers to situations in which financial or other personal considerations, circumstances, or relationships may compromise, may involve the potential for compromising, or may have the appearance of compromising an Investigator's objectivity in fulfilling Research Responsibilities.

Immediate Family Member: includes an Investigator's spouse, domestic or civil union partner, and dependent children.

Investigator: means the principal investigator, project director, key personnel and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of research activities. This may also include research study coordinators, research assistants, graduate students, students and others. The term investigator is not intended to apply to individuals who primarily provide technical support, administrative support, or who are purely advisory, such that these individuals have no influence over the research results (e.g., control over its collection, analysis or reporting).

Public Health Service (PHS): means the section of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority of the PHS may be delegated. The components of the PHS include, but are not limited to, the Centers for Disease Control and Prevention, Food and Drug Administration, Indian Health Service, National Institutes of Health.

Funding overseen by the financial conflict of interest regulations is issued by the Department of Health and Human Services (DHHS) and administered by the National Institute of Health (NIH) ***Significant Financial Interest:*** Significant Financial Interest includes an external financial interest consisting of one or more of the following interests of an Investigator (and those of the Investigator's Immediate Family Members) related to their Institutional Responsibilities, when combined for the 12 months preceding the disclosure date, from a single Entity:

Nature of Significant Financial Interest	Disclosure Threshold
Remuneration, compensation, and/or other payments for services (e.g., consulting, speaking)	Exceeds $5,000
Equity interests in a publicly-traded entity	Exceeds $5,000
Equity interests in a non-publicly-traded entity (e.g., a start-up company)	0 / Any
Intellectual property rights and interests	Exceeds $5,000
Sponsored or reimbursed travel	Exceeds $5,000

Disclosure of sponsored or reimbursed travel applies to PHS funded researchers only

Significant Financial Interests do **NOT** include:

(1) Salary, royalties or other remuneration paid by Campbell University to the Investigator if the Investigator is currently employed or otherwise appointed by the University;

(2) Intellectual property rights assigned to Campbell University and agreements to share in royalties related to such rights;

(3) Equity interests through investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;

(4) Income from seminars, lectures or teaching engagements sponsored by a federal, state or local government agency, a qualifying institution of higher education, an academic teaching hospital, a medical center or a research institute that is affiliated with a qualifying institution of higher education;

(5) Income from service on advisory committees or review panels for a federal, state or local government agency, a qualifying institution of higher education, an academic teaching hospital, a medical center or a research institute that is affiliated with a qualifying institution of higher education; or

(6) Sponsored or reimbursed travel sponsored or paid by a federal, state or local government agency, a qualifying institution of higher education, an academic teaching hospital, a medical center or a research institute that is affiliated with a qualifying institution of higher education.

Requirements and Principal Investigator Responsibilities

Research Investigators and any project team members are required to disclose Financial Conflicts of Interest or other interest that are/or may be perceived to be related to the research on the *New Protocol Submission Form* for IRB review and approval. If there is a potential or perceived conflict related to the protocol, the Principal Investigator is asked if the conflict has been disclosed and/or managed on the *IRB Conflict of Interest Form*. Conflicts of Interest should be reported, in advance and prior to IRB protocol submission, to the Principal Investigator's Department Chair and other institutional officials as outlined in the Campbell University's Faculty/Personnel Manual prior to being forwarded to the Office of Sponsored Research and Programs (OSRP).

Investigators and project team members submitting research applications to the IRB are required to submit the *IRB Conflict of Interest Form*, when a conflict of interest has been ***identified, disclosed and/or managed*** for the investigator and project team members with the conflict of interest. The following must be included on the *IRB Conflict of Interest Form*:

- Significant financial interest that could directly and significantly affect the design, conduct or reporting of Campbell University research activities; or
- Any situation that could directly and significantly affect the design, conduct or reporting of human research activities or the researchers profession commitments or allegiance to Campbell University. These situations may include but are not limited to family collaborations on the project, outside employment in a field similar or directly related to the research, committee/board member roles similar or directly related to the research and reimbursed or sponsored travel.

All potential conflicts of interest should be reported to the IRB. It is up to the IRB, not the person holding the potential conflict of interest or any other study team member, to decide if these can affect the design, conduct or reporting of the study. The Principal Investigator is responsible for maintaining conflict of interest records for the entire research team and updating of conflict of interest disclosures.

Procedures

1. Disclose financial conflicts of interest or other conflicts of interest that are or may be perceived to be related to the research protocol in Section 10 of the *New Protocol Submission Form* for IRB review and approval, if there is a potential or perceived conflict related to the protocol.
2. Submit an IRB Conflict of Interest Disclosure form for all research team members as attachments to the *New Protocol Submission Form*, if there is a potential or perceived conflict related to the protocol.
3. Submit revised *IRB Conflict of Interest Disclosure Form(s)* as required to an IRB Approved Protocol using an *Amendment Submission Form*, if there has been a change

to potential or perceived conflict of interest. Changes in conflicts of interest are to be submitted within 30 days of acquiring the change in conflict of interest.

IRB Review

The IRB's function is to ensure that subject protection, the integrity of IRB review, and the conduct of research is not jeopardized by an unidentified or unmanaged conflict of interest. IRB approval is not granted until the OSRP has been notified that the COI disclosures have been reviewed and any management actions required are agreed to by the investigator.

The IRB determines whether the stipulations for managing the COI adequately protect the rights and welfare of human participants or whether additional actions are necessary to minimize risks. The IRB determines the kind, amount, and level of detail of information the principal investigator must provide the participants in the informed consent process regarding source of funding, funding arrangements, financial interest of parties involved in research, and any techniques applied to manage financial COI. Actions required to mitigate actual or perceived conflictions of interest identified or suspected upon initial review of a research protocol will depend on the nature and seriousness of the perceived conflict. Actions taken by the IRB may require minimizing or discharge conflicts of interest may include but are not limited to any of the following:

- Modification of the protocol procedures or the roles of specific project team members.
- Independent safety monitoring and/or review of research data and methods of data analysis.
- Divestiture of significant financial interest.
- Reassignment, suspension or termination of specific roles of project team members.
- Withdrawal from all or part of the research project of one or more project team members.
- If the IRB has agreed to rely on an External IRB per an Institutional Authorization Agreement (IAA), the process describe above should still be followed. The researchers must disclose the conflict of interest to the IRB of Record (sIRB) according to the process agreed upon between the CU IRB and the IRB of Record (sIRB) and comply with any conflict of interest management plans that may result.

IRB Review of Conflicts of Interest at External Sites

If the CU IRB is serving as the IRB of Record (sIRB) for another organization through an Institutional Authorization Agreement (IAA) or under the conditions of an approved cooperative agreement, the investigators will be subject to their organization's or institution's policies of conflicts of interest.

Investigator's at other relying organizations or institutions are required to identify any financial interests that they have disclosed according to their organization's policies and provide the CU IRB with any applicable conflict of interest determinations and managements plans conducted at the relying institution. The CU IRB retains the authority to impose additional prohibitions or conflict of interest management requirements more stringent or restrictive than proposed by the

relying organization or institution if necessary. However, the CU IRB will not modify or change any management plan or mandate disclosure to participants without discussion with an acceptance by the relying organization or institution.

References

- HRPP Policy: Human Research Protection Program Plan
- National Science Foundation, Grant Policy Manual, NSF 05-131.510 July 2005, Conflict of Interest Policy
- 42 CFR Part 50, Subpart F