

Financial Conflicts of Interest in Sponsored Research

Date of Current Revision: February 11, 2021

Primary Responsible Officer: Director of Sponsored Research and Programs



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Policy Title:	Financial Conflicts of Interest in Sponsored Research	Revised Date(s):	February 11, 2021
Policy Type:	<input type="checkbox"/> Board <input checked="" type="checkbox"/> Administrative <input type="checkbox"/> Academic <input type="checkbox"/> Student <input type="checkbox"/> Other: _____	Contact:	Vincenzo Cassella, Director of Sponsored Research and Programs

Policy Statement
<p>Campbell University, Incorporated ("Campbell University") encourages its Investigators to participate in research activities and to do so with the highest ethical standards. While the potential for conflicts of interest to arise in research is understandable due to the innovative and entrepreneurial pursuits of our research community, we must identify and manage situations in which financial or other personal interests could impact, bias or compromise – or have the appearance of biasing or compromising – objectivity or judgment relative to research. Investigators who are involved in approved (see § IV.J of the Personnel Manual) outside consulting or business activities must clearly separate their Campbell University and outside obligations in order to avoid concerns as to their appropriate use of University resources and contributions by other Campbell University personnel. Investigators must be open about their involvement with and obligations to outside parties and should provide students, staff, and colleagues with information about the funding that supports their research.</p>

Purpose:	<p>This Policy on Financial Conflicts of Interest in Sponsored Research ("Policy") provides guidelines to promote objectivity in research. The Policy establishes standards to ensure that the design, conduct, and reporting of research funded by extramural sponsors will not be biased by any conflicting financial interest of an Investigator. Campbell University encourages Investigators to engage in appropriate outside relationships, but significant financial interests related to these relationships must be disclosed, reviewed, and managed in accordance with this Policy.</p>
Procedure:	<p>1.0 Training</p> <p><i>Prior to starting</i> to work on a funded project, personnel involved in projects funded by the Public Health Service (including NIH, CDC, NSF, and others) must complete training on financial conflicts of interest. The required Collaborative Institutional Training Initiative (CITI) training course is web-based and easily accessed. While the PHS is the only agency with the training requirement as of now, <i>Campbell University requires</i> that all investigators complete the CITI FCOI training.</p> <p>Investigators involved in research funded by sponsors subject to this Policy <i>must complete required</i> conflict of interest training before engaging in research and every three (3) years thereafter. A sponsor may require training more frequently than indicated by this Policy. If there is a substantive change in this Policy or specific instances of noncompliance, additional training may also be required.</p>

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**2.0 Disclosure****2.1 What Must Be Disclosed?**

Each Investigator must personally complete and submit a Financial Conflict of Interest in Sponsored Research Disclosure Form to disclose any Significant Financial Interests that reasonably appear to be related to the Investigator's Institutional Responsibilities. For the purposes of this Policy, a 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
Remuneration received from a publicly-traded entity	Exceeds \$5,000
Equity interest in a publicly-traded entity	Exceeds \$5,000
Remuneration received from a non-publicly-traded entity (e.g., a start-up company)	Exceeds \$5,000
Equity interest in a non-publicly-traded entity	Any (no minimum)
Intellectual property rights and interests	Any (no minimum)
Sponsored or reimbursed travel	Exceeds \$5,000

Disclosure of sponsored or reimbursed travel applies to Public Health Service (PHS) funded researchers only, and must include: the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

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) Income from 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) Travel reimbursed or 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.



Investigators participating in research funded by the Public Health Service (PHS) must also disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their responsibilities to the University; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

2.2 Who Must Disclose?

Any individual involved in the design, conduct, or reporting of research covered under this Policy, regardless of title or position, is an Investigator and must satisfy the requirements of this Policy. For purposes of this Policy, individuals meeting the definition of Investigator may include University employees, postdoctoral and clinical fellows, graduate students, and/or others who assume independent responsibility for the design, conduct, or reporting of research covered under this Policy. The Principal Investigator is responsible for designating which individuals involved in specific research activities meet the definition of Investigator.

2.3 When is Disclosure Required?

Prior to submitting a proposal to an external funding agency and at other times as specified in the Policy and implementing procedures, all persons involved in the design, conduct, and reporting of the proposed project *must disclose* any significant financial interests they hold that are related to their institutional responsibilities. *Investigators must disclose* Significant Financial Interests prior to engaging in sponsored research, within 30 days of discovery or acquisition of a new Significant Financial Interest, and at least annually if required by the sponsor (even if acknowledging no change to previous disclosures). Investigators must perform initial and ongoing disclosures of Significant Financial Interests in Campbell University's conflict of interest disclosure form [\[hyperlink\]](#).

3.0 **Review**

Significant Financial Interests disclosure forms are reviewed by Campbell University's Office of Sponsored Research and Programs (OSRP) as part of the grant application package. Forms will be reviewed in the context of each research project on which an individual is an Investigator. Conflict of interest review will include an analysis of the nature and extent of an Investigator's role on a project, the nature and extent of an Investigator's Significant Financial Interest(s), and the nature of the sponsored research activity under review. These reviews are conducted to assess whether or not Significant Financial Interests of an Investigator relate to and could directly and significantly affect the design, conduct, or reporting of research, thus presenting a Financial Conflict of Interest relative to the sponsored research, or an appearance thereof. Additionally, a specific review will be conducted to determine if the disclosed interest meets the federal definition of a Financial Conflict of Interest.

The Office of Sponsored Research & Programs performs an initial review of all Investigator disclosures of Significant Financial Interests relative to all applicable

sponsored research projects. OSRP makes determinations of referrals to the Provost and the Conflict of Interest Official, on a research project by research project basis.

The Research Ethics and Compliance Committee Chair or a designee appointed by the Provost will serve as the Conflict of Interest Official to perform the duties required by this policy and other duties as assigned by the Provost. The Provost and the Conflict of Interest Official review the Significant Financial Interest(s) to determine if the Significant Financial Interest(s) presents a Financial Conflict of Interest for the related sponsored research activity or have the ability to directly and significantly affect the design, conduct, or reporting of the research.

Reviews and determinations must occur prior to expenditure of funds for new projects and within 60 days of newly-disclosed Significant Financial Interests. Additionally, reviews and determinations must occur within 60 days of the addition of new Investigators to projects during the life of a project.

4.0 Management

If a Financial Conflict of Interest determination is made, the Provost and the Conflict of Interest Official (working with Investigators and others as needed) develop a conflict of interest management plan to manage, reduce, or eliminate the Financial Conflict of Interest. Conflict of interest management plans are strategies designed to mitigate the potential for an Investigator's Significant Financial Interests to impact, compromise, or bias research objectivity and/or the safety or welfare of human research participants.

Conflict of interest management plans could include disclosure of the Financial Conflict of Interest (to study teams, collaborators, the Institutional Review Board, human research participants, and in presentations and publications), a reduced role in the research, and/or independent review of research data and results. Additional conflict of interest management strategies may be employed depending on the nature of the Financial Conflict of Interest and the nature of the sponsored research activity. In extreme cases, an Investigator may be prohibited from participating in sponsored research due to the level and extent of Significant Financial Interests deemed to present a Financial Conflict of Interest relative to specific sponsored research activity. Investigators must acknowledge agreement to conflict of interest management plans in order to engage in sponsored research for which Financial Conflict of Interest determinations are made.

Financial Conflict of Interest in Sponsored Research determinations are made, and conflict of interest management plans are implemented, by the Provost and the Conflict of Interest Official. However, it is in the purview of Campbell University's respective institutional compliance committee chairs to review and approve the conflict of interest management strategies associated with their respective areas to include, but not limited to:

- Institutional Review Board (IRB)
- Institutional Animal Care and Use Committee (IACUC)
- Institutional Biosafety Committee (IBC)

Institutional compliance committee chairs or designees will review the conflict of interest management strategies associated with protocols and determine whether or not

the conflict of interest management is sufficient. The conditions of and compliance with Investigator conflict of interest management plans are reviewed on at least an annual basis by the Provost and Conflict of Interest Official, if applicable. On an *ad hoc* basis, the Provost, Conflict of Interest Official and/or the Research Ethics and Compliance Committee also conducts independent monitoring and verification to ensure that the conditions of conflict of interest management plans are being met.

5.0 Appeals

Any decision of the Provost and the Conflict of Interest Official concerning the existence of a conflict of interest or the appropriateness of a plan to manage, reduce, or eliminate a conflict may be appealed within thirty (30) business days to a panel which shall include the Provost or designee, Conflict of Interest Official, Research Ethics and Compliance Committee and appointed representatives. The decision of the panel shall be final.

6.0 External Reporting

The Office of Sponsored Research & Programs administers and oversees all external conflict of interest reporting for Campbell University in accordance with federal and individual sponsor requirements. Some external sponsors, such as PHS, require Campbell University to provide initial and ongoing reports relative to an Investigator's Financial Conflict of Interest determinations as they relate to specific research activities. For Financial Conflicts of Interests relative to PHS-funded research, the Office of Sponsored Research & Programs must perform the required conflict of interest reporting prior to the expenditure of funds for new projects, within 60 days of newly-determined Financial Conflicts of Interest identified during the life of a project, and on an annual basis thereafter prior to progress report submission during the life of a project. In addition, PHS requires Campbell University to make available to the public, upon request, specific information regarding Financial Conflicts of Interest determined for senior and key personnel relative to PHS-funded research. Campbell University is required to provide specific information relative to such public requests within five business days of the request.

7.0 Subrecipients

Campbell University must apply relevant originating sponsor conflict of interest requirements to subrecipients. Therefore, Campbell University must identify whether or not a subrecipient has a conflict of interest policy compliant with applicable originating sponsor conflict of interest requirements. If a subrecipient does not have a conflict of interest policy compliant with applicable originating sponsor conflict of interest requirements, in order to proceed with the Campbell University collaboration, the subrecipient must agree to abide by this Policy relative to the subrecipient investigators and the specific subrecipient research activity for the duration of that activity. The subrecipient agreement must incorporate terms that establish whether the conflict of interest policy of Campbell University or that of the subrecipient will apply to subrecipient investigators, and obligations of the subrecipient relative to conflict of interest in either case.

8.0 Noncompliance

The following are examples of noncompliance with this Policy:

- a) Failure to submit a timely disclosure;
- b) Submission of an incomplete, erroneous or misleading initial, updated or annual disclosure;
- c) Failure to disclose information as required by this Policy; or



	<p>d) Failure to comply with prescribed management plans.</p> <p>Any instances of Investigator noncompliance may require that the Investigator repeat Campbell University's required conflict of interest training module. Additional disciplinary action for noncompliance with this Policy will be decided in accordance with applicable Campbell University disciplinary policies and procedures as outlined in the Faculty Handbook, the Personnel Manual, and other relevant policies. Ramifications for noncompliance could include restrictions relative to proposing and engaging in Campbell University research and/or an internal review of the research, as well as other disciplinary action up to and including termination.</p> <p>For instances of noncompliance involving PHS-funded research, whenever a Financial Conflict of Interest is not identified or managed in a timely manner, including failure by the Investigator to disclose a Significant Financial Interest, or failure of an Investigator to comply with the conditions of a conflict of interest management plan, Campbell University must conduct a retrospective review of the Investigator's research activities on the project to determine if there is an impact, compromise, bias in the design, conduct, or reporting of the research resulting from the Financial Conflict of Interest. The retrospective review must be completed within 120 days of the determination of noncompliance. If an impact, compromise, or bias is found in the course of the retrospective review, Campbell University must promptly notify PHS and submit a mitigation report that addresses the impact, compromise, or bias on the research and the University's plan of action to eliminate or mitigate the effect of the bias. Additionally, for instances of noncompliance noted above involving PHS-funded clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, the Investigator is thereafter required to disclose the Financial Conflict of Interest in each public presentation of the results of the relevant research and also request an addendum to previously published presentations of the relevant research.</p> <p>9.0 Confidentiality</p> <p>Subject to Section 6.0 of this Policy, access to information collected in connection with this Policy will be limited to those with a need to know and will be shared in accordance with Campbell University policies and federal regulations.</p> <p>10.0 Record Retention</p> <p>Conflict of interest records relative to sponsored research covered under this Policy must be maintained for a period of three years after any applicable research project's final financial report is submitted to the sponsor, until three years after the final action has been taken on any audit, litigation, or claim, or as outlined in the sponsor's retention policy, whichever is longer.</p> <p>11.0 Roles and Responsibilities</p> <p>11.1 Investigators</p> <p>Investigators are responsible for engaging in research design, conduct, and reporting that is free from an impact, compromise, or bias resulting from conflicts of interest. Investigators have an obligation to meet initial and ongoing conflict of interest training and disclosure requirements and comply with the conditions of conflict of interest management plans, if applicable.</p> <p>11.2 Conflict of Interest Official</p>
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	<p>Campbell University's Research Ethics and Compliance Committee Chair or a Provost-appointed designee serves as the Conflict of Interest Official to oversee and implement the University's faculty, staff, research, and institutional conflict of interest in sponsored research policies and procedures, ensures compliance with applicable conflict of interest regulatory requirements, provides guidance and support to the Campbell University community regarding conflict of interest policies, systems, standards, and procedures, and administers and supports the activities of the Research Ethics and Compliance Committee. The Research Ethics and Compliance Committee, in collaboration with the Office of Sponsored Research, ensures that principal investigators complete the required conflict of interest training and disclosure requirements and performs initial reviews of Investigators' Significant Financial Interests in the context of sponsored research activities. The Provost is the institutional Chief Academic Officer for conflict of interest and fulfills Campbell University's conflict of interest reporting requirements to federal agencies, external sponsors, and the public when required with the assistance of the Office of Sponsored Research & Programs.</p> <p>11.3 Research Ethics and Compliance Committee</p> <p>The role of the Research Ethics and Compliance Committee, or entity designated by the Provost, includes review and resolution of institutional conflicts of interest, as well as conflict of interest issues arising through annual or periodic disclosures that cross school or Faculty/Staff boundaries and conflict of interest matters referred from the Research Ethics and Compliance Committee Chair or Conflict of Interest Official. The Research Ethics and Compliance Committee also ensures consistent application of this Policy throughout the University. Furthermore, the Research Ethics and Compliance Committee may recommend changes, as needed, to this Policy. The Research Ethics and Compliance Committee is comprised of representatives from academic and key relevant offices within central administration.</p>
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Scope:	Investigators who submit applications for research funding to any federal or industry sponsors, or other sponsors that have conflict of interest requirements, and/or Investigators engaged in research involving human research participants, regardless of funding source, are subject to the training, disclosure, review, and management requirements of this Policy unless otherwise specified in this Policy. Investigators funded by the Public Health Service (PHS) and/or other agencies that abide by PHS COI regulations are subject to additional requirements as specified in this Policy.
Exclusions:	To the extent that any external sponsor's standards are more stringent than this Policy, the sponsor's requirements will take precedence.
Enforcement:	Office of the Provost Research Ethics and Compliance Committee
Publication:	This Policy is published on the university website.
Duration:	This Policy remains in effect until further notice.
Review Period:	Reviewed annually by the Research Ethics and Compliance Committee.
Definitions:	Entity: For the purposes of this Policy, an Entity is an external business, company, or other such organization, and includes (but is not limited to) any partnership, corporation, limited

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liability corporation, unincorporated association, or other institution or organization, whether for-profit, academic, or professional.

Financial Conflict of Interest (FCOI): means a Financial Interest that could directly and significantly affect the design, conduct, or reporting of research.

Human Subject Research: means any systematic investigation (1) that is designed to develop or contribute to generalizable knowledge and (2) obtains data through intervention or interaction with living individuals and/or obtains identifiable private information about living individuals, including by means of the observation or recording of behavior. Intervention includes both physical procedures and manipulations of the subject or subject's environment that are performed for study purposes. Interaction includes communication or interpersonal contact between an investigator and a subject. Private information includes information that individuals can reasonably expect will not be made public. This definition also encompasses any experiment that involves a test article and one or more human subjects (i.e., a "clinical investigation" per FDA regulations).

Immediate Family Member: For the purposes of this Policy, Immediate Family Member includes an Investigator's spouse, domestic or civil union partner, and dependent children.

Institutional Responsibilities: For the purposes of this Policy, Institutional Responsibilities include professional activities that relate to an Investigator's responsibilities on behalf of Campbell University, such as research, teaching, institutional committee memberships, professional practice, and administrative activities and responsibilities for Campbell University.

Investigator: For the purposes of this policy, 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 their 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, Environmental Protection Agency, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and Substance Abuse and Mental Health Services Administration.

Research: a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge, including basic and applied research and product development

Reimbursed or Sponsored Travel: means any travel that is not covered directly through the University and for which an Investigator either receives direct reimbursement from, or is covered by, an external entity. For the purposes of this Policy, reimbursed or sponsored travel is only applicable to PHS funded Investigators.

Significant Financial Interest: means Significant Financial Interest as defined in section 2.1 of this Policy.

Subrecipient: For the purposes of this Policy, a Subrecipient is a legal entity that receives a Subcontract from a pass-through entity to carry out a portion of a sponsored program. A Subrecipient has responsibility for programmatic decision making; has its performance measured in relation to whether objectives of a programmatic scope of work were met; and is responsible for adherence to applicable sponsored program requirements specified in the

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	sponsored award, as opposed to providing routine goods or services for the benefit of the pass-through entity. Students: "Students" means students, trainees, and post-doctoral fellows.
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SACSCOC:	SACSCOC Standard 13.5
Accreditation:	SACSCOC Standard 13.5
Related Forms, Policies, or Tools:	<p>Financial Conflict of Interest (FCOI) in Research Disclosure Form - https://www.campbell.edu/about/leadership/provost/sponsored-research-programs/policies-procedures-and-guidelines/</p> <p>Collaborative Institutional Training Initiative (CITI) Module - http://www.citiprogram.org/</p> <p>The following federal regulations inform this policy:</p> <p>Public Health Service (PHS) - http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf</p> <p>National Institutes of Health (NIH) - NIH Financial Conflict of Interest Page</p> <p>National Science Foundation (NSF) - http://www.nsf.gov/pubs/policydocs/pappguide/nsf10_1/aag_4.jsp</p> <p>Food and Drug Administration (FDA) - https://www.fda.gov/RegulatoryInformation/</p>

To determine approval level, please consult your respective Vice President.

Reviewed By:	Dayton Cole	Title:	Interim General Counsel	Date:	02/11/2021 11/30/2020
	Michael Mahalik		Research Integrity Officer		02/08/2021 11/10/2020
	Borrée Kwok		Assistant Provost for Administration		02/11/2021 11/06/2020
Approved By:	Executive Cabinet	Title:		Date:	02/15/2021
Last Updated By:	Vincenzo Cassella	Title:	Director of Sponsored Research and Programs	Date:	02/10/2021
	K. Victoria Ming		Research Compliance Officer		02/05/2021

Keywords (up to 8):	Research, Conflict of Interest, Significant Financial Interest
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