

Western Research

Western University - Research Development & Services
Policies and Procedures

RD&S POLICY RD&S Procedures

FINANCIAL CONFLICTS OF INTEREST (FCOI) COMPLIANCE FOR US PUBLIC HEALTH SERVICE (PHS) AGENCIES

PURPOSE

The purpose of this policy is to ensure compliance by Western University (“Western”) and researchers to [US 42 C.F.R. Part 50 Subpart F](#) “Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought”.

POLICY

The design, conduct and reporting of research at Western University must be free of bias or perception of bias as a result of financial conflict of interest. Persons conducting research at Western must comply with all applicable policies related to research including this policy when research funding is received from the United States Public Health Service (“PHS”), either directly or indirectly as a sub-recipient or where the funding entity requires compliance with the same regulations as PHS.

SCOPE

This policy applies to all Investigators and Senior/Key Personnel who are planning to participate in, or are participating in any research funded by the PHS through a grant or cooperative agreement between Western and a PHS Awarding Component or a funding entity who requires compliance with the regulations applicable to PHS research funding.

DEFINITIONS

- a) “Designated Official” means the person(s) designated by the University, through the Vice President Research and International, to oversee the solicitation and review disclosures of significant financial interests from each Investigator and any Senior/key personnel who are planning to participate in, or who are participating in PHS funded research. Western’s Designated Official (rwrngo@uwo.ca).
- b) “Disclosure” means an Investigator’s disclosure of SFIs to the University.
- c) “Financial Conflict of Interest” or “FCOI” means an SFI that could directly and significantly affect the design, conduct, or reporting of PHS funded research.
- d) “Financial Interest” means anything of monetary value, whether or not the value is readily ascertainable.
- e) “Institutional Responsibilities” means an Investigator’s professional responsibilities on behalf of the University, the responsibilities of the Investigator pursuant to the policies, procedures and rules of the University, and (as applicable) any other responsibilities outlined in the Investigator’s job description, employment agreement or appointment letter with the University. This includes, (as applicable), activities

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such as research, research consultation, teaching, professional practice, institutional committee memberships and service on panels such as the Research Ethics Boards or Data and Safety Monitoring Boards.

f) “Investigator” means the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of PHS funded research, or proposed for such funding, which may include, for example, collaborators or consultants. Investigator also includes Senior/key personnel identified as such by the University in the grant application, progress report, or any other report submitted to the PHS by the University under this Policy.

g) “Manage” means taking action to address a FCOI, which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

h) “PHS” means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health.

i) “PHS Awarding Component” means the organizational unit of the PHS that funds research that is subject to the PHS Regulations.

j) “PHS Regulations” means the US Regulations 42 C.F.R. Part 50 and 45 C.F.R. Part 94, as they may be amended from time to time.

k) “Senior/key personnel” means a project director, or principal Investigator of a PHS funded project and any other person identified as senior/key personnel by the University in the grant application, progress report or any other report submitted to the PHS by the University.

l) “Significant Financial Interest” or “SFI” means:

(i) A Financial Interest consisting of one or more of the following interests of the Investigator (and those of the Investigator’s spouse and dependent children that reasonably appears to be related to the Investigator’s Institutional Responsibilities:

- With regard to any publicly traded entity, a Significant Financial Interest exists if the value of any remuneration received from the Entity in the twelve months preceding the Disclosure and the value of any equity interest in the entity as of the date of Disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
- With regard to any non-publicly traded entity, a Significant Financial Interest exists if the value of any remuneration received from the entity in the twelve months preceding the Disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator’s spouse or dependent children) holds any equity interest (e.g. stock, stock option, or other ownership interest); or
- Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(ii) For the purposes of making a Disclosure, Investigators also must disclose the Occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not

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reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their Institutional Responsibilities; provided, however, that this Disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, State or local government agency, a US institution of higher education, an academic teaching hospital, a medical centre, or a research institute that is affiliated with an institution of higher education. This Disclosure will include, at a minimum; the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

The Designated Official(s) will determine if further information is needed, including a determination or Disclosure of monetary value, in order to determine whether the travel constitutes a FCOI with the PHS funded research.

(iii) Exclusions: The term Significant Financial Interest does not include the following types of Financial Interests:

- salary, royalties, or other remuneration paid by the University to the Investigator if the Investigator is currently employed or otherwise appointed by the University, including intellectual property rights assigned to the University and agreements to share in royalties related to such rights;
- 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;
- income from seminars, lectures, or teaching engagements sponsored by a Federal, State or local government agency, a US institution of higher education, an academic teaching hospital, a medical centre, or a research institute that is affiliated with an institution of higher education; or
- income from service on advisory committees or review panels for a Federal, State or local government agency, a US institution of higher education, an academic teaching hospital, a medical centre, or a research institute that is affiliated with an institution of higher education.

m) “Subrecipient” means a third party organization (subcontractor or subawardee) that receives funding from a prime awardee (i.e., Western) to collaborate in carrying out an externally funded research project. Monies and responsibilities are passed down to a Subrecipient through a subaward or subcontract that outlines the scope of work, budget and laws and regulations that the Subrecipient must adhere to.

n) “Subrecipient Investigator” means an Investigator who is planning to participate in, or who is participating in any research funded by the Public Health Service through a subaward or subcontract between the University and a Subrecipient.

PROCEDURES/REQUIREMENTS

A number of US Public Health Service (PHS) agencies, including the NIH, have implemented stringent requirements pertaining to the reporting of Significant Financial Interests (SFIs) and the reporting and management of Financial Conflicts of Interest (FCOI) that affect all investigators and co-investigators, their spouses and their dependent children. The intended purpose of these PHS requirements is to promote objectivity in the design, conduct and reporting of PHS-sponsored research.

In order to remain eligible for funding, investigators applying for or holding PHS grants must follow the steps outlined below. The process of each step is detailed in the [RD&S Procedures](#) on *Financial Conflicts of Interest (FCOI) in Public Health Service (PHS) Funded Research*.

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RELATED REFERENCES

Western MAPP 7.2 Consulting Fees Paid for Services of a Researcher
Western MAPP 3.4 Conflicts of Interest

Relevant US Regulations:

2011 Public Health Service (PHS) Regulations: Responsibility of Applicants for Promoting Objectivity in Research for Which PSH Funding is Sought ([42 C.F.R. Part 50, Subpart F](#))

Other applicable [PHS regulations](#)

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