



UNIVERSITY OF WESTERN ONTARIO
INSTITUTIONAL PROCEDURES

FOR COMPLIANCE WITH THE U.S. PUBLIC HEALTH SERVICE
FINANCIAL CONFLICT OF INTEREST REGULATION

I. INTRODUCTION AND APPLICATION OF THESE INSTITUTIONAL PROCEDURES:

These Institutional Procedures are made under the University of Western Ontario (“Western”) Policy on [Academic Integrity in Research Activities, MAP](#) effective date September 24, 2013, and are supported by the [UWOFA Collective Agreement 2018-2022](#), Article Academic Responsibilities of Members. These Institutional Procedures set out the obligations of Western with respect to Investigator Financial Conflicts of Interest (FCOIs) (defined below) where research is funded by the U.S Public Health Service (PHS), which includes the National Institutes of Health (NIH) and other awarding components of the PHS.

These Institutional Procedures should be read in conjunction with the [Investigator Procedures for Compliance with the U.S. Public Health Service Financial Conflict of Interest Regulation](#) “Investigator Procedures”. The purpose of the Investigator Procedures is to inform Investigators of their obligations and of FCOI processes, including some relevant obligations of Western.

Together, the Institutional Procedures and the Investigator Procedures implement the requirements of

II. DEFINITIONS:

Designated Official: The individual(s) in the Research Ethics & Compliance Office of Western's Office of the Vice-President, Research portfolio, are responsible for the review of Significant Financial Interests (SFI), the determination of whether an FCOI exists, and the approval of management plans under these Institutional Procedures.

Financial Conflict of Interest (FCOI): A Significant Financial Interest or Sponsored Travel (both defined below) that could directly and significantly affect the design, conduct or reporting of PHS-funded research.

Financial Interest: Anything of monetary value received or held by an Investigator or any member of the Investigator's immediate family (specifically, any dependent children or spouse or common law partner), whether or not the value is readily ascertainable. Financial Interests include salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works), equity interests (e.g., stocks, stock options, or other ownership interests), and intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights) upon receipt of royalties or other income related to such intellectual property rights and interests.

Investigator: Any person, regardless of title or position, who is responsible for the design, conduct, or reporting of PHS-funded research (whether or not they are paid from PHS funds). This includes, but is not limited to, the principal Investigator (PI) or project director (PD), and may include postdoctoral associates, research staff, students, collaborators, or consultants.

Professional Responsibilities: An Investigator's professional responsibilities on behalf of Western, which may include, for example, activities such as research, research consultation, teaching, professional practice, administrative activities and institutional committee memberships (see Article Academic Responsibilities of Members [UWOFA Collective Agreement 2018-2022](#)).

Program Director/Principal Investigator (PD/PI): The individual(s) designated by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program to be supported by the award. The applicant organization may designate multiple individuals as program directors/principal investigators (PD/Pis) who share the authority and responsibility for leading and directing the project, intellectually and logistically. When multiple PD/Pis are named, each is responsible and accountable to the applicant organization, or as appropriate, to a collaborating organization for the proper conduct of the project or program including the submission of all required reports. The presence of more than one PD/PI on an application or award diminishes neither the responsibility nor the accountability of any individual PD/PI. Western's PHS FCOI Investigator Procedures apply to individuals who meet the 'Investigator' definition, which includes, but is not limited to, PD/Pis.

Senior/key Personnel: The principal Investigator or project director, and any other person identified as senior/key personnel by Western in the grant application, progress report, or any other report submitted to the PHS by Western under the FCOI Regulation (or, in the case of a research contract for the U.S. government, any other person identified as senior/key personnel in the contract proposal and contract).

III. UNIVERSITY OBLIGATIONS:

The institution

C. Review of Disclosed SFIs and Determination of FCOIs

- 1) Provide guidelines consistent with these Institutional Procedures and the FCOI Regulation for the Designated Official to determine whether an Investigator's SFI is related to PHS- funded research and, if so, whether the SFI is an FCOI.
- 2) Review all Investigator SFI disclosures (including those of a subrecipient Investigator, if applicable) to determine whether any SFIs relate to PHS-funded research. An Investigator's SFI is related to PHS-funded research when the Designated Official reasonably determines that the SFI could be affected by the PHS-funded research, or is in an entity whose financial interest could be affected by the research. Western may involve the Investigator in the Designated Official's determination of whether an SFI is related to the PHS-funded research. The decision of the Designated Official is final.
- 3) For each SFI that is found to be related to PHS-funded research, determine if an FCOI exists, i.e. whether the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research. The decision of the Designated Official is final.
- 4) Where a FCOI is found to exist, take such actions as are necessary to manage the FCOI, including developing and implementing a management plan, and, where required, conducting a retrospective review (see section E below).
- 5) Conduct and complete the review and determinations described in paragraphs 2) and 3) above and take any action required to manage the FCOI within the following timelines:
 - a) prior to Western's expenditure of any funds; and
 - b) during an ongoing research project, within 60 days of any of the following events:
 - i. an Investigator who is new to participating in the research project discloses an SFI;
 - ii. an existing Investigator discloses a new SFI; or
 - iii. Western identifies an SFI that was not disclosed in a timely manner by an Investigator, or that was not previously reviewed by Western (e.g., was not reported by a sub-recipient).

D. Management of FCOIs

- 1)

complete (within 120 days of determining non-compliance) a retrospective review of the Investigator's activities and the research project in order to determine whether any of the research conducted during the time of non-compliance was biased in its design, conduct or reporting.

- 2) During the retrospective review, impose, if necessary (depending on the nature of the FCOI), additional interim measures regarding the Investigator's participation in the research project pending completion of the review.
- 3) Document the retrospective review, including, at minimum, the following key elements:
 - a) project number and title;
 - b) PD/PI (or contact PD/PI if a multiple PD/PI model is used);
 - c) name of the Investigator with the FCOI;
 - d) name of the entity with which the Investigator has an

b) a description of the impact of the bias on the research project (e.g., extent of harm done, including any qualitative and quantitative) (e) (001 Tc 0.003 1960.228 0

- iii. name of the entity in which the SFI is held;
 - iv. nature of the SFI; and
 - v. approximate dollar value of the SFI (dollar ranges are permissible: \$US0-\$4,999 USD; \$5,000 USD-\$9,999 USD; \$10,000 USD-\$19,999 USD; amounts between \$20,000 USD-\$100,000 USD by increments of \$20,000 USD; amounts above \$100,000 USD by increments of \$50,000 USD), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.
- b) be provided by a written response within 5 business days of a written request, and include up-to-date information;
 - c) state in the written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of Western's identification of a new FCOI, which should be requested subsequently by the requestor; and
 - d) remain available for at least 3 years from the date of the request.