

UNIVERSITY OF WESTERN ONTARIO
INVESTIGATOR PROCEDURES

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

I. INTRODUCTION AND APPLICATION OF INVESTIGATOR PROCEDURES:

These Investigator Procedures are made under the University of Western Ontario Policy on Academic Integrity in Research Activities, MAP 07, effective date September 24, 2013, and are supported by the JWOFA Collective Agreement 2012, Article Academic Responsibilities of Members

The University of Western Ontario ("Western") is committed to the highest standards of academic integrity and ethical conduct. These procedures are designed to ensure compliance with the U.S. Public Health Service Financial Conflict of Interest Regulation and to maintain the integrity of our research activities.

Together, the investigator

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 PHSCOI Investigator Procedures apply to those that meet the Investigator definition, which includes, but is not limited to PD/PIs.

- f 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 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).
- f Significant Financial Interest (SFI): A Financial Interest that reasonably appears to be related to the Investigator's Professional Responsibilities:
 1. with regard to a publicly traded entity, the aggregate value of any salary or other payments for services received from the entity during the 12 month period preceding the disclosure plus the value of any equity interest in the entity as of the date of disclosure exceeds \$5,000 USD
 2. with regard to a nonpublicly traded entity:
 - a) the aggregate value of any salary or other payments for services received from the entity during the 12 month period preceding the disclosure exceeds

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a) What to Disclose

Investigators must disclose their Significant Financial Interests (including Sponsored Travel). If an Investigator is not sure whether a particular Financial Interest is significant and should be disclosed, they should disclose it.

Parts IV and V below ~~so~~ out the actions Western and the PHS will take to ensure

The decision of the Designated Official is final.

4) Management of FCOIs and Management Plans

Where an FCOI is found to exist, West will 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 below).

The principal Investigator and the Chair and/or Dean of the Investigator's academic unit (or delegate) will develop a management plan, in consultation as appropriate with the Investigator determined to have an FCOI. The management plan must specify the actions that have been and will be taken to manage the FCOI, including a mechanism for monitoring compliance with the management plan until the completion of the subject research project, and will be subject to the approval of the Designated Official. The management plan will specify who is responsible for implementing the management plan and monitoring Investigator compliance until completion of the research. This will ordinarily (but not always) be the Chair or Dean of the Investigator's academic unit (or delegate).

In addition, where an FCOI was not identified or managed in a timely manner (including failure by the Investigator to disclose an SFI that is determined to be an FCOI or to comply with an FCOI management plan), Westermill, within 120 days of determination of non-compliance, complete a retrospective review of the Investigator's activities and the research project to determine whether the research conducted during the period of non-compliance was biased in its design, conduct or reporting.

6)

iii. the nature and approximate dollar value of the ~~SI~~.

8) Other Obligations of the ~~University~~

In addition to the specific obligations set out above, Western will comply with all other institutional obligations mandated by the ~~FCB~~ Regulation (and set out in the Institutional Procedures), including, but not limited to, the following:

- i. posting these Investigator Procedures and the Institutional Procedures on the publicly accessible website of the ~~Vice President, Research~~ (Western Research) ~~e10.7 (w)-6.4 (e)-693 (t)-5.9 (e)- 0.02-plnh~~

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Financial Administration

f Western Financial Services/US Federal Award Requirements

f Western Financial Services/Procurement Services/Ethical Procurement Practices

f UWO Procurement Code of Ethics

(Last revised: May, 2021)