



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 THESE PROCEDURES:

These Investigator Procedures are made under the University of Western Ontario Policy on [Academic Integrity in Research Activities, MAPP 7.0](#), effective date September 24, 2013, and are

Together, the Investigator

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.

Disclosure of Sponsored Travel must include the purpose of the trip, the identity of the sponsor/organizer, the destination and the duration, and any other relevant information that the University might require (including monetary value).

Annual updates must include any information not previously disclosed and updated information regarding previously disclosed SFIs.

b) When to Disclose

Disclosure must be made:

- i. no later than at the time of application for funding from the PHS (or, in the case of a s.6 (fra 421.04 14990.467 ()10.6q.6 (o)-6.6 (f)10.5 (ap10.2 (dr)-1P)-5.8 (H7

The decision of the Designated Official is final.

4) Management of FCOIs and Management Plans

Where an FCOI is found to exist, Western 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 5 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).

Examples of conditions or restrictions that might be imposed to manage an FCOI include, but are not limited to:

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), Western will, 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 conductedit perdu-6.4 (h)esearp01 Tc 7t.7 (c)- In

iii. the nature and approximate dollar value of that SFI.

8) Other Obligations of the University

In addition to the specific obligations set out above, Western will comply with all other institutional obligat

with the FCOI Regulation. The PHS awarding component may determine that imposition of special award conditions, and/or suspension of funding or other enforcement action, is necessary until the matter is resolved.

VI. ADDITIONAL RESOURCES

1) U.S.Regulations

- x [Promoting Objectivity in Research](#)

2) NIH Resources

NIH has provided the following educational documents with in-depth information on the conditions under which a disclosure must be made with respect to FCOIs concerning PHS funds:

- x [NIH Financial Conflict of Interest overview](#)
- x [Frequently Asked Questions \(FAQs\): Responsibility of Applicants for Promoting](#)

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Financial Administration

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