

# Western Research

## 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 INVESTIGATOR 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 supported by the [UWOFA Collective Agreement 2018-2022](#), Article *Academic Responsibilities of Members*.

The University of Western Ontario (“Western”) is committed to ensuring the highest standards of ethical conduct in every aspect of research. Those undertaking academic work (which include faculty, students and anyone holding a university post or any office that gives university status, such as that of a fellow or a research associate) shall strive to follow the best research practices honestly, accountably, openly and fairly in the search for and in the dissemination of knowledge. Individuals are personally responsible for the intellectual and ethical integrity of their work and must ensure that in research their conduct meets University standards and best practices, professional and disciplinary standards, applicable laws and regulations, and the integrity standards of any entities sponsoring any component of research work.

Where research is funded by the U.S. Public Health Service (PHS), which includes the National Institutes of Health (NIH), the following U.S. regulation regarding Financial Conflicts of Interest (FCOI) applies: [42 CFR 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought"](#) (FCOI Regulation), as implemented in the [2011 Final Rule](#) for grants and cooperative agreements. The purpose of the FCOI regulation is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under PHS grants, cooperative agreements and contracts will be free from bias resulting from Investigator FCOIs.

The FCOI Regulation applies to all institutions, both U.S. and foreign, applying for or receiving PHS research funding, including funding that is received as a sub-award from another institution, and to each Investigator (defined below) participating, or planning to participate, in such research. All contracts and grants from PHS awarding components, such as NIH, require Western to agree to be bound by the FCOI Regulation as a condition of funding.

These Investigator Procedures set out the obligations of Investigators under the FCOI Regulation, as well as applicable FCOI processes, where research is funded by the PHS.

Companion Procedures, the *Institutional Procedures for Compliance with the U.S. Public Health Service Financial Conflict of Interest Regulation*, (the “Institutional Procedures”), set out the obligations of Western with respect to Investigator FCOIs where research is funded by the PHS.

Together, the Investigator Procedures and the Institutional Procedures implement the requirements of the FCOI Regulation with regard to PHS-funded research at Western. One of the requirements of the Regulation is that Western must have a written enforced policy on FCOIs for PHS-funded research that complies with the Regulation. The Investigator Procedures and the Institutional Procedures together fulfill that requirement.

Anyone who chooses to apply for or accept PHS funding (through Western) or to work on a PHS-funded research project and who meets the definition of Investigator below must comply with these Investigator Procedures and, through them, the FCOI Regulation. Failure to comply can mean risk of serious consequences, including suspension or termination of funding.

In addition to the PHS and its components, some other U.S. sponsors of research, including some U.S. foundations, have adopted the PHS FCOI Regulation. Where the terms of those sponsors' funding contracts or grants require Western to adhere to the FCOI Regulation, these Investigator Procedures, as necessarily modified for context, will apply.

## 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 Investigator 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 of [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 logically. 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 those that 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 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).
- **Significant Financial Interest (SFI):** A Financial Interest that reasonably appears to be related to the Investigator's Professional Responsibilities and:
  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 non-publicly 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 \$5,000 USD; or,
    - b) the Financial Interest is an equity interest in the entity of any value; or,
  3. with regard to intellectual property rights and interests (e.g. patents and copyrights), related income of any value (upon receipt of such income).

Sponsored Travel (defined below) is a Significant Financial Interest for the purpose of Parts III to V of these Investigator Procedures.

The following are **not** Significant Financial Interests:

- salary, royalties, or other remuneration received from Western by Investigators employed by or appointed at Western;
- income from the authorship of academic or scholarly works;
- income from seminars, lectures, or teaching engagements sponsored by (or from service on advisory committees or review panels for) U.S. federal, state or local governmental agencies, and U.S. institutions of higher education and affiliated research institutes, academic teaching hospitals, and medical centres; or,
- income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles.

- **Sponsored Travel:** Any reimbursed or sponsored travel undertaken by the Investigator that is related to the Investigator's Professional Responsibilities, including travel that is paid on behalf of the Investigator, even if the exact monetary value is not readily available, but not including travel reimbursed or sponsored by U.S. federal, state or local governmental agencies, and U.S. institutions of higher education and affiliated research institutes, academic teaching hospitals, and medical centres. Sponsored Travel is a Significant Financial Interest for the purpose of Parts III to V of these Investigator Procedures.

### III. INVESTIGATOR OBLIGATIONS:

#### 1) Training

Investigators must make themselves familiar with these Investigator Procedures and signify (via Western's Financial Interests Disclosure Report, or in another manner as required by Western) that they have read and understood these Procedures and agree to comply with them before engaging in any PHS- funded research, and must do so again at least every 4 years.

Investigators must also complete the [NIH On-Line FCOI Tutorial \(2018\)](#) for the PHS FCOI Regulation regarding grants before engaging in any PHS-funded research and must do so again at least every 4 years. When the NIH tutorial is completed, Investigators fill in their name for a certificate and save a copy. A copy of the certificate must be forwarded to the appropriate Grants or Contracts Officer at Western Research ([researchoffice@uwo.ca](mailto:researchoffice@uwo.ca)) to ensure that Western can track who has completed training.

Additional training may be required, including when an Investigator joins Western or Western revises these Investigator Procedures, or if an Investigator is not in compliance with these Investigator Procedures or a management plan.

Access to PHS funds may be suspended or otherwise withheld until Investigators have completed the required training.

#### 2) Disclosure Of SFI

Any Investigator planning to participate (or participating) in PHS-funded research or applying for or receiving PHS funds (whether directly or through a subcontract) must disclose to Western's Designated Official their SFIs and any SFIs of their spouse, common law partner or dependent children.

The principal Investigator is responsible for ensuring that all Investigators involved in their PHS-funded research project are aware of these Investigator Procedures and make any disclosures required by these Investigator Procedures.

**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 sub-award, from the prime institution) and be current within one year;
- ii. at least annually during the period of the PHS award (to update previously disclosed SFIs);
- iii. within 30 days of discovering or acquiring a new SFI; and
- iv. when a new Investigator joins an ongoing project.

**c) How to Disclose**

All Investigators must complete and forward a signed **Financial Interests Disclosure Report (FIDR)** to Western Research ([researchoffice@uwo.ca](mailto:researchoffice@uwo.ca)). Should an Investigator disclose a SFI, the responsible Grants or Contracts Officer will forward the FIDR to the Designated Official for review and determination of whether there is an FCOI.

Investigators should refer to the FIDR form for further instructions for its completion and submission.

Where applicable, Investigators must make reasonable efforts to obtain from the entity or individual in which the Investigator has an SFI consent for disclosure of personal or confidential information and forward such consent to Western Research ([researchoffice@uwo.ca](mailto:researchoffice@uwo.ca)) along with the FIDR.

**3) Compliance and Remedies**

Investigators must comply with these Investigator Procedures and with any management plan developed to manage an FCOI.

Contravention of these Investigator Procedures, including failure to reveal SFIs or failure to abide by any management plan, may constitute research misconduct under the University's [MAPP POLICY 7.0 – Academic Integrity in Research Activities](#) and/or the [UWOFA Collective Agreement 2018-2022](#).

Parts IV and V below set out the actions Western and the PHS will take to ensure compliance and the remedies they can impose in the event of non-compliance.

In the event of non-compliance, access to PHS funds may be suspended and remedial actions and/or sanctions applied in accordance with Western's applicable policies and procedures.

In any case in which the U.S. Department of Health and Human Services (HHS) determines that clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported by Western as required, Western must require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

In addition to these Investigator Procedures and any management plan, Investigators conducting PHS- funded research also remain subject to all of Western's applicable policies and procedures, including without limitation, those with respect to conflict of interest, financial management and research involving human participants. (See the list in Part VI below.)

#### **IV. UNIVERSITY OBLIGATIONS:**

##### **1) Introduction**

Western's obligations (including processes and timelines) under the FCOI Regulation are set out fully in the Institutional Procedures.

##### **2) The Designated Official**

The FCOI Regulation requires that Western designates a Designated Official to solicit and review disclosures of SFIs and determine if an FCOI exists.

##### **3) Review of SFIs**

The Financial Interests Disclosure Reports that Investigators submit are reviewed by the Designated Official to determine whether any disclosed SFIs relate to the PHS-funded research and, if so, whether an FCOI exists.

An Investigator's SFI is related to PHS-funded research when the SFI could be affected by the PHS-funded research or is in an entity whose financial interest could be affected by the research. An FCOI exists when the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

The Designated Official will consult with the Chair and/or Dean of the Investigator's academic unit (or delegate) and may request further information from the Investigator and consult confidentially with the Investigator and others as necessary.

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:

- i. public disclosure of FCOIs (e.g., when presenting or publishing the research);
- ii. for research projects involving human subjects research, disclosure of FCOIs directly to participants;
- iii. appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias, resulting from the FCOI;
- iv. modification of the research plan;
- v. change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- vi. reduction or elimination of the Financial Interest (e.g., sale of an equity interest); or
- vii. severance of relationships that create financial conflicts.

#### **5) Retrospective Review**

If Western identifies an SFI that was not disclosed in a timely manner by an Investigator or, for whatever reason, was not previously reviewed by Western during an ongoing research project, Western will, within 60 days, review the SFI to determine whether it is an FCOI and, if so, implement a management plan.

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 conducted during the period of non-compliance was biased in its design, conduct or reporting.

## 6) Reports to PHS Awarding Components

Western will report any FCOI determined to exist, together with any applicable management plan, to the PHS awarding component as required by the Regulation. In particular, reports will be made:

- i. before any PHS funds are spent;
- ii. within 60 days of the identification of new FCOIs; and,
- iii. annually for the duration of the research to update the status of the FCOI and any changes to an applicable management plan (normally at the same time as the annual or multi-year progress report is due).

Investigators must cooperate with Western in providing all required reports and related information to the PHS awarding components.

Where a retrospective review is conducted, Western will update the FCOI report to the PHS awarding component as appropriate, and if Western finds bias, it will promptly notify the PHS awarding component and submit a mitigation report to the PHS awarding component, which will include actions taken to eliminate or mitigate the effect of the bias.

The information that must be included in reports is set out in the FCOI Regulation and in the Institutional Procedures.

## 7) Public Accessibility of FCOI information

Information concerning FCOIs where the individual with the SFI is Senior/key Personnel (as defined in Part II above) must be accessible to the public, be updated in accordance with the Regulations, and remain publicly available for at least 3 years.

Information concerning any such SFI may be requested in a written request addressed to the Institutional Delegate and Western will provide a written response within 5 business days.

The information will include at minimum:

- i. the Investigator's name, title and role with respect to the research project;
- ii. the name of the entity in which the SFI determined to constitute an FCOI is held; and,

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 obligations mandated by the FCOI 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).
- ii. taking reasonable steps to ensure that a subrecipient (e.g., subcontractor or consortium members) and its Investigators comply with the Regulation by incorporating compliant FCOI terms into the written agreement and reporting FCOIs of subrecipient Investigators to the PHS awarding component
- iii. providing guidelines for the Designated Official for determining whether the SFI is related to the research and, if so, whether it is an FCOI
- iv. making information available, promptly upon request, to PHS and/or HHS relating to any Investigator SFI disclosure and Western's review of, and response to, such disclosure (whether or not an FCOI was found to exist); and
- v. maintaining records relating to all Investigator SFI disclosures and Western's review of, and response to, such disclosures and all actions taken (whether or not an FCOI was found to exist) in accordance with the FCOI Regulation (ordinarily for at least 3 years from the date the final expenditures report is submitted or, in the case of a contract, from the date of the final payment).

## **V. PHS POWERS**

The FCOI Regulation sets out the following powers of the PHS and its awarding components:

Where Western has notified the PHS awarding component that an Investigator has failed to comply with these Investigator Procedures or a management plan and the design, conduct, or reporting of the PHS-funded research appears to have been biased (as per Part IV, paragraph 6 above), the PHS awarding component will consider the situation and, as necessary, take appropriate action, or refer the matter to Western for further action, which may include directions on how to maintain appropriate objectivity in the PHS-funded research project.

The PHS awarding component (and/or HHS) may inquire at any time before, during, or after the award into any Investigator disclosure of SFIs and Western's review (including any retrospective review) of, and response to, such disclosure, regardless of whether the disclosure resulted in Western's determination of an FCOI. Western is required to submit, or permit on site review of, all pertinent records. To the extent permitted by law, the PHS awarding component (and/or HHS) will maintain the confidentiality of all records of SFIs. On the basis of its review of records or other information that may be available, the PHS awarding component may decide that a particular FCOI will bias the objectivity of the PHS-funded research to such an extent that further corrective action is needed or that Western has not managed the FCOI in accordance

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

- [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:

- [NIH Financial Conflict of Interest overview](#)
- [Frequently Asked Questions \(FAQs\): Responsibility of Applicants for Promoting Objectivity in Research \(2011 Revised Regulations\)](#)
- [What NIH Grantees Need to Know About the 2011 Revised Financial Conflict of Interest Regulation](#)
- [NIH Grants Policy Statement – 4.1.10 Financial Conflict of Interest](#)

### 3) Other University Policies and Procedures

Investigators should be aware of the following policies and procedures at Western:

#### Conduct of Research

- [Academic Integrity in Research Activities](#) is governed by MAPP 7.0
- Western provides [online responsible conduct of research training](#)
- University Secretariat – [Rights and Responsibilities](#)
- [Certification Compliance for Research Funds](#)
- [UWOFA Collective Agreement 2018-2022 \(PDF\)](#), applicable Articles, but not limited to: *Academic Fraud and Misconduct, Academic Responsibilities of Members, Conflict of Interest and Conflict of Commitment, Discipline*

#### Conflict of Interest

- [Western Research Conflict of Interest](#)
- [MAPP 3.4 – Conflicts of Interest](#)
- [UWOFA Collective Agreement 2018-2022 \(PDF\)](#), applicable Articles, but not limited to: *Academic Fraud and Misconduct, Academic Responsibilities of Members, Conflict of Interest and Conflict of Commitment, Discipline*.

**Financial Administration**

- Western Financial Services – [US Federal Award Requirements](#)
- Western Financial Services/Procurement Services – [Ethical Procurement Practices](#)
- [UWO Procurement Code of Ethics](#)

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