

Western Research

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, MAPP 7.0](#), 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* (the “*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 [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 is applicable 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 participating (or planning to participate) in such research. All contracts and grants from PHS awarding components require Western to agree to be bound by the FCOI Regulation as a condition 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 Institutional Procedures, as necessarily modified for context, will apply.

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

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 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 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).

- **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 Institutional 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 Institutional Procedures.

III. UNIVERSITY OBLIGATIONS:

The institutional obligations of Western with respect to PHS-funded research (and research funded by non-PHS agencies adhering to PHS policies) under the FCOI Regulation are set out in sections A to J below.

The office of the Vice-President, Research (VPR) is responsible for meeting these obligations on behalf of Western. The VPR portfolio will establish (where not already established) such processes and positions as are required to meet these obligations, and will maintain and comply with the processes on an ongoing basis.

A. Investigator Training

- 1) Inform each Investigator of these Institutional Procedures and the Investigator Procedures, including posting the two (2) Procedures on the Western Research website, and require each Investigator to signify that they have read the Investigator Procedures and agrees to comply with them.
- 2) Require each Investigator to complete the [NIH On-Line FCOI Tutorial \(2018\)](#) for the Regulation regarding grants and to obtain an online certificate of completion, a copy of which must be forwarded to Western Research (researchoffice@uwo.ca).
- 3) Require each Investigator to complete the training set out in 1) and 2) above at each of the following times:
 - a) prior to engaging in research related to any PHS-funded grant;
 - b) at least every 4 years; and
 - c) immediately, if:
 - i. Western revises the Investigator Procedures in a way that affects the obligations and/or rights of Investigators,
 - ii. an Investigator is new to Western; or
 - iii. an Investigator is not in compliance with the Investigator Procedures or a management plan.

B. Disclosure of SFIs by Investigators

- 1) Require each Investigator/subrecipient Investigator who is planning to participate (or is participating) in PHS- funded research to disclose to Western their SFIs in accordance with the Investigator Procedures at the following times:
 - a) no later than at the time of application for PHS-funded research;
 - b) at least annually during the period of the award (to update previously disclosed SFIs); and
 - c) within 30 days of discovering or acquiring a new SFI.
- 2) Details regarding the disclosure obligations for Investigators are set out in the Investigator Procedures.

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) Implement a management plan (to be developed by the principal Investigator and the head of their academic unit (or delegate) and approved, possibly with amendments, by the Designated Official) that specifies actions taken and to be taken to manage the FCOI.
- 2) Ensure that the management plan includes the following key elements:
 - a) role and principal duties of the conflicted Investigator in the research project;
 - b) conditions of the management plan (see paragraph 3) below);

- c) how the management plan is designed to safeguard objectivity in the research project;
 - d) confirmation of the Investigator's agreement to the management plan;
 - e) how the management plan will be monitored to ensure Investigator compliance; and
 - f) other information as needed.
- 3) Impose appropriate conditions or restrictions to manage the FCOI(s); these could include, but are not limited to, the following:
- a) public disclosure of the FCOI (e.g., when presenting or publishing the research);
 - b) for research projects involving human participant research, disclosure of the FCOI directly to participants;
 - c) 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;
 - d) modification of the research plan;
 - e) change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
 - f) reduction or elimination of the Financial Interest (e.g., sale of an equity interest); or
 - g) severance of relationships that create the FCOI;
 - h) any other reasonable condition or restriction to ensure that the FCOI is properly managed.
- 4) Where an SFI is disclosed during an ongoing research project (by a new Investigator or a new SFI by an existing Investigator), impose, if necessary (depending on the nature of the SFI), interim measures regarding the Investigator's participation in the research project pending completion of the review.
- 5) Monitor Investigator compliance with the management plan until completion of the research project.

E. Retrospective Review

- 1) Whenever it is discovered that an FCOI was not identified or managed in a timely manner, including:
- a) failure by an Investigator to disclose an SFI in a timely manner, where the SFI, once disclosed, was reviewed (as per Section C above) and determined by Western to constitute an FCOI;
 - b) failure by Western to review an SFI or manage an FCOI; or
 - c) failure by an Investigator to comply with a management plan,

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 FCOI;
 - e) reason(s) for the retrospective review;
 - f) detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
 - g) findings of the review; and
 - h) conclusions of the review.
- 4) Based on the results of the retrospective review, update, if appropriate, the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward.
- 5) If bias is found:
 - a) notify the PHS awarding component promptly of the corrective action taken or to be taken; and
 - b) submit a mitigation report to the PHS awarding component (see section F, paragraph 3) below).
- 6) After the initial reports described in paragraphs 4) and 5) above, submit FCOI update reports annually, as specified in section F below.

F. Reporting and Notifications to PHS Awarding Components

- 1) Send initial, annual (i.e., ongoing) and revised FCOI reports (for Western and for subrecipients, if applicable) to the PHS awarding component as required by these Institutional Procedures, at the following times:
 - a) prior to the expenditure of any PHS funds (no report should be sent if the FCOI is eliminated before any funds are spent); and
 - b) subsequent to the initial FCOI report, during an ongoing research project:

- i. within 60 days of identification (by a Western review as per section C above) of an FCOI for an Investigator who is newly participating in the project;
 - ii. within 60 days for a new, or newly identified (by a Western review as per section C above), FCOI for an existing Investigator ;
 - iii. at least annually (in the time and manner specified by the PHS awarding component), to provide the status of any previously reported FCOI and any changes to the management plan (if applicable), until the completion of the project. The report must explain how the FCOI is being managed or why it no longer exists;and
 - iv. following a retrospective review (as per section E above), to update a previously submitted report, if appropriate.
- 2) Include in any FCOI report sufficient information to enable the PHS awarding component to understand the nature and extent of the FCOI, and to assess the appropriateness of Western's management plan. Elements of the FCOI report shall include, but are not necessarily limited to, the following:
 - a) project number;
 - 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 FCOI;
 - e) nature of the Financial Interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
 - f) value of the Financial Interest (dollar ranges are permissible: \$0 USD-\$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;
 - g) a description of how the Financial Interest relates to the PHS-funded research and the basis for Western's determination that the Financial Interest conflicts with such research; and
 - h) a description of the key elements of Western's management plan (see section D, paragraph 2) above).
- 3) Send a mitigation report to the PHS awarding component following a retrospective review where bias is found. The report must include, at a minimum:
 - a) the key elements documented in the retrospective review (see section E, paragraph 3) above);

- b) a description of the impact of the bias on the research project (e.g., extent of harm done, including any qualitative and quantitative data to support any actual or future harm, and analysis of whether the research project is salvageable); and
 - c) Western's plan of action (or actions taken) to eliminate or mitigate the effect of the bias.
- 4) Notify the PHS awarding component promptly if a retrospective review results in a finding of bias, including the corrective action taken or to be taken.
 - 5) Make information relating to disclosures of SFIs, and Western's review, determination and action taken, available to the PHS or HHS promptly on request, whether or not an FCOI was found to exist.

G. Compliance, Enforcement Mechanisms and Remedies

- 1) Certify in each application for PHS funding that Western shall fully comply with the FCOI Regulation.
- 2) Establish as necessary and utilize adequate enforcement mechanisms and employee sanctions or other administrative actions to ensure Investigator compliance.
- 3) Implement management plans and take other actions under these Institutional Procedures to manage FCOIs or non-compliance.
- 4) In any case in which the US Department of Health and Human Services (HHS) determines that a PHS-funded project of 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 as required by the FCOI Regulation, Western must require the Investigator involved to:
 - a) disclose the FCOI in each public presentation of the results of the research; and
 - b) request an addendum to previously published presentations.

H. Requirements Regarding Subrecipients

- 1) When Western carries out PHS-funded research through a subrecipient (e.g., subcontractors or consortium members), take reasonable steps to ensure that subrecipient Investigators comply with the Regulation by establishing, in a written agreement with the subrecipient, whether the subrecipient's Investigators will be subject to the FCOI policy of the subrecipient or to Western's Investigator Procedures with respect to the research.
- 2) If the subrecipient's FCOI policy applies:
 - a) require the subrecipient to certify in the subrecipient agreement that its FCOI policy complies with the Regulation. (If the subrecipient cannot so certify, the agreement must state that Western's Procedures apply); and
 - b) specify in the subrecipient agreement a time period for the subrecipient to report all identified FCOIs of its Investigators to Western that allows Western

sufficient time to provide FCOI reports to the PHS awarding component as required by the FCOI Regulation.

- 3) If Western's Procedures apply, specify in the subrecipient agreement a time period for the subrecipient to submit all Investigator disclosures of SFIs to the University that allows Western sufficient time to review the SFIs and manage and report identified FCOIs to the PHS awarding component as required by these Institutional Procedures.

I. Maintenance of Records

- 1) Maintain records related to all disclosures of SFIs and reviews and action taken (whether or not an FCOI is found to exist) for at least 3 years from the date the final expenditures report is submitted to the PHS awarding component (or, in the case of a contract, the date of the final payment), with the following exceptions:
 - a) if any litigation, claim, financial management review, or audit is started before the expiration of the 3-year period, the records must be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken, or until the end of the regular 3-year period, whichever is later;
 - b) records for real property and equipment acquired with PHS funds must be retained for 3 years after final disposition;
 - c) when records are transferred to or maintained by the PHS awarding component, the 3-year retention requirement is not applicable to Western; and
 - d) for records relating to indirect cost rate proposals, cost allocations plans, etc.:
 - i. if the proposal, plan, or other computation must be submitted for negotiation of the rate, then the 3-year retention period for its supporting records starts on the date of such submission; or
 - ii. if there is no requirement to submit the proposal, plan, or other computation for negotiation purposes, then the 3-year retention period for records starts at the end of the fiscal year (or other accounting period) covered by the proposal, plan, or other computation.

J. Public Accessibility of Information

- 1) Post and maintain these Institutional Procedures and the Investigator Procedures on the Western Research publicly accessible website.
- 2) Prior to the expenditure of any PHS funds, make information concerning any disclosed SFI that is held by Senior/key Personnel and has been determined to be an FCOI publicly accessible. The information will:
 - a) include the following minimum elements as required by the Regulations:
 - i. name of the Investigator with the FCOI;
 - ii. Investigator's title and role with respect to the research project;

- 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 the information was most recently updated.

IV. PHS POWERS:

- 1) Where Western notifies the PHS awarding component of a finding of bias (as per Part III, section F, paragraph 4) 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.
- 2) 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.