

<b>Policy:</b>	Financial Conflict of Interest for U.S. Public Health Service Funded Research - Lawson				
<b>Policy Owner:</b>	IVP, Research				
<b>Approval By:</b>	Chief Operating Officer, Research Lawson	<b>Approval Date:</b>	2021-09-14		
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<b>Related Policy at St. Joseph's:</b>	Financial Conflict of Interest for U.S. Public Health Service Funded Research – Lawson				

## POLICY

The design, conduct and reporting of research at Lawson Health Research Institute (Lawson) must be free of bias or perception of bias as a result of [financial conflict of interest \(FCOI\)](#). Persons conducting research at Lawson must comply with all applicable policies related to research including this policy when research funding is received from the United States [Public Health Service \(PHS\)](#) either directly or indirectly as a [sub-recipient](#) or where the funding entity requires compliance with the same regulations as PHS. Adherence to this policy ensures Lawson's and researchers' compliance with US 42 C.F.R. Part 50 Subpart F "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought".

This policy applies to all [investigators](#) and [senior/key personnel](#) who are planning to participate in, or are participating in any research funded by the PHS through a grant or cooperative agreement between Lawson and a [PHS Awarding Component](#) or a funding entity who requires compliance with the regulations applicable to PHS research funding ([Public Health Service \(PHS\) Regulations: Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought \(42 C.F.R. Part 50, Subpart F\)](#)).

This policy supplements existing research related conflict of interest, commitment and research conduct policies applicable to Lawson researchers through Lawson, Western University (including Schulich School of Medicine and Dentistry), London Health Sciences Centre, St. Joseph's Health Care London and applicable professional associations and/or professional colleges.

## PROCEDURE

1. [Disclosure\(s\)](#) must be filed by all investigators who are applying for, receiving, or working on a project with, PHS funding or funding from an entity requiring compliance with [PHS regulations](#) whether directly or as a sub-recipient. Disclosure(s) must be in writing to the [Designated Official](#) at Lawson of all [significant financial interests \(SFIs\)](#) that they, and their spouse and dependent children have using the Financial Interests Disclosure Report ([Appendix A](#)), at the following times:
  - 1.1. Initial Disclosure
    - 1.1.1. Prior to the time of application for [PHS funded research](#) in accordance with such timelines as are stipulated by the Designated Official, for all SFIs in the 12 months preceding the disclosure.
  - 1.2. Ongoing Disclosure
    - 1.2.1. Within 30 days of discovering or acquiring a new SFI (including but not limited to a purchase, marriage, inheritance etc.), and
    - 1.2.2. On an annual basis during the term of the PHS funded research, disclosure of all SFIs received in the 12 months preceding the disclosure that were not previously reported, and updated information regarding any previously disclosed SFI.
- 1.3. All investigators who are new to Lawson/Western University and are applying for and/or receiving PHS funding or who are participating in a PHS funded research project must make the initial disclosure and ongoing disclosures as noted above.

2. Each investigator must complete mandatory training consisting of the [National Institutes of Health \(NIH\) Financial Conflict of Interest Tutorial](#) prior to engaging in PHS-funded research or research funded by an entity requiring compliance with PHS regulations, at the request of Lawson acting reasonably, and every four years thereafter so long as such funding continues. Upon completion of the tutorial, a certificate of completion becomes available which must be saved by the Investigator with an e-copy sent to the Designated Official.
3. The Designated Official must review all disclosures of SFIs from investigators including [sub-recipient investigators](#), within the timeframes noted in [Section 4](#), and determine whether any disclosed SFIs relate to the PHS funding and whether any SFI is a FCOI. The Designated Official may involve the Investigator in the determination of whether an SFI is related to PHS funded research. The Designated Official's determination that a SFI is a FCOI is final.
4. The Designated Official must complete review and determination noted in [Section 3](#) according to the following times:
  - 4.1. Prior to Lawson's expenditure of any funds under a PHS funded research project,
  - 4.2. Within 60 days, whenever, in the course of an ongoing PHS funded project, an investigator or sub-recipient investigator who is new to participating in the project discloses a SFI or an existing investigator or sub-recipient investigator discloses a new SFI to Lawson, and
  - 4.3. Within 60 days whenever Lawson identifies a SFI that was not disclosed in a timely manner by an investigator or sub-recipient investigator or, for whatever reason, was not previously reviewed by Lawson during an ongoing PHS funded research project.
5. The Designated Official, on behalf of Lawson, must maintain records related to all investigator disclosures of SFIs and Lawson's review of, and response to, such disclosures (whether or not a disclosure resulted in Lawson's determination of a FCOI) and all actions under this policy for at least the later of three (3) years from the date the final expenditures report is submitted to the PHS Awarding Component, the date of final payment, or where applicable such other time period as specified.
6. If the Designated Official determines through the review noted in [Section 3](#) that there is a FCOI, the Designated Official must prepare a plan to [manage](#) the FCOI.
  - 6.1. The Designated Official, in consultation with the IVP, Research, may involve an ad hoc committee to support development of such FCOI management plan. Such ad hoc committee will be comprised of those stakeholders relevant to the situation, for example Lawson's Scientific Director, the Research Ethics Board Chair, hospital Risk Management, the Investigator's Department or Division Chair/Chief, a senior representative of Western University or Schulich School of Medicine and Dentistry (the "Committee"). The Designated Official and/or Committee may request an audience with the Investigator in order to clarify details of the disclosure. Disclosure(s) will be treated in confidence to the extent possible and shared only as necessary to support the work of the Designated Official and the Committee.
  - 6.2. Key elements of the management plan shall include:
    - 6.2.1. Role and principal duties of the conflicted Investigator in the research project,
    - 6.2.2. Conditions of the management plan,
    - 6.2.3. How the management plan is designed to safeguard objectivity in the research project,
    - 6.2.4. Confirmation of the Investigator's agreement to the management plan,
    - 6.2.5. How the management plan will be monitored to ensure investigator compliance, and
    - 6.2.6. Additional elements deemed necessary by the Designated Official and/or Committee to ensure the FCOI is managed.
  - 6.3. Examples of conditions or restrictions required by a management plan include but are not limited to:
    - 6.3.1. Public disclosure of the FCOI (e.g. when presenting or publishing research),
    - 6.3.2. For research projects involving humans, disclosure of the FCOI directly to the participants,
    - 6.3.3. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from a FCOI,
    - 6.3.4. Modification of the research plan;
    - 6.3.5. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
    - 6.3.6. Reduction or elimination of the [financial interest](#) (e.g. sale of an equity interest), or
    - 6.3.7. Severance of the relationships that create the FCOI.

7. The Investigator is required to comply with the management plan prescribed by the Designated Official.
8. On behalf of Lawson, the Designated Official must monitor compliance with the management plan on an ongoing basis until the completion of the project.
9. Reporting Requirements to the PHS Awarding Component
  - 9.1. Lawson must provide initial and ongoing FCOI reports (when applicable) after the award is granted but prior to the expenditure of any funds under a PHS funded research project, and at least annually, thereafter.
  - 9.2. All reports must be submitted in the time and manner specified by the PHS Awarding Component for any other FCOI reports for the duration of the project period (including extensions with or without funds).
  - 9.3. For any FCOI previously reported by Lawson, the report must address the status of the FCOI and any changes to the management plan for the duration of the PHS Funded Research project. The annual FCOI report must specify whether the financial conflict is still being managed or explain why the FCOI no longer exists.
  - 9.4. Lawson must provide FCOI reports to the PHS Awarding Component regarding all FCOIs of all sub-recipient Investigators prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.
  - 9.5. FCOI reports by Lawson/Western University must include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of Lawson's management plan. Each FCOI report prepared by the Designated Official on behalf of Lawson must contain:
    - 9.5.1. Grant number,
    - 9.5.2. Project director/principal Investigator or contact project director/principal Investigator if a multiple project director/principal Investigator model is used,
    - 9.5.3. Name of Investigator with the FCOI,
    - 9.5.4. Name of the entity with which the Investigator has a FCOI,
    - 9.5.5. Nature of FCOI (e.g. equity, consulting fees, travel reimbursement, honoraria),
    - 9.5.6. Value of the financial interest per year:
      - 9.5.6.1. \$5,000-\$9,999,
      - 9.5.6.2. \$10,000-\$19,999,
      - 9.5.6.3. Amounts between \$20,000-\$100,000 by increments of \$20,000,
      - 9.5.6.4. Amounts above \$100,000 by increments of \$50,000, or
      - 9.5.6.5. A statement that a value cannot be readily determined.
    - 9.5.7. A description of how the financial interest relates to the PHS Funded Research and the basis for Lawson's determination that the financial interest conflicts with such research, and
    - 9.5.8. Key elements of the FCOI management plan.
10. If Lawson intends to carry out aspects of the PHS Funded Research with a sub-recipient, then Lawson must take reasonable steps to ensure that the written agreement with the Sub-recipient includes terms to establish whether this policy or the Sub-recipient's own FCOI policy will apply to the Sub-recipient and Sub-recipient Investigators. If the Sub-recipient's FCOI policy is to apply, then Lawson shall obtain from the Sub-recipient a certification that the Sub-recipient's policy complies with the PHS Regulations. If this policy is to apply, then the written agreement with the Sub-recipient shall so indicate and specify reporting requirements on sub-recipient investigator SFIs.
11. Under the PHS Regulations, Lawson is required to make information publicly accessible:
  - 11.1. The current version of this policy shall be maintained on Lawson's publicly accessible website.
  - 11.2. After an award of PHS Funded Research has been granted, but prior to Lawson's expenditure of such funds, Lawson shall make available through Lawson's publicly accessible website the information listed in [Section 11.3](#) concerning any SFI that meets the following criteria:
    - 11.2.1. SFI was disclosed and is still held by the Investigator who has been identified by Lawson as senior/key personnel for the PHS Funded Research project in the grant application, contract, progress report, or other required report submitted to the PHS Awarding Component,
    - 11.2.2. Lawson, through the Designated Official, determines that the SFI is related to PHS Funded Research, and

11.2.3. Lawson, through the Designated Official determines that the SFI is a FCOI.

11.3. Lawson must post on Lawson's publicly accessible website the following minimum information concerning any SFI that meets the criteria outlined in [Section 11.2](#):

11.3.1. Investigator's name;

11.3.2. Investigator's role with respect to the PHS Funded Research project;

11.3.3. nature of the SFI;

11.3.4. approximate dollar value of the SFI:

11.3.4.1. \$5,000-\$9,999,

11.3.4.2. \$10,000-\$19,999,

11.3.4.3. Amounts between \$20,000-\$100,000 by increments of \$20,000,

11.3.4.4. Amounts above \$100,000 by increments of \$50,000 or

11.3.4.5. A statement that a value cannot be readily determined.

11.3.5. The entity with which the Investigator has a FCOI.

11.4. The Designated Official shall update the publicly accessible information within 60 days of changes to this information and at a minimum annually. This information shall remain available on Lawson's publicly available website for at least three (3) years from the date the information was most recently updated.

12. If an investigator fails to comply with this policy or a FCOI management plan, Lawson, through the Designated Official, shall promptly notify the PHS Awarding Component of corrective action to be taken. Such actions may include, but are not limited to, formal admonition, notification of investigator's institutional leadership, suspension of institutional authorization, ineligibility of the Investigator to conduct Lawson Research, addendum to previous publications disclosing FCOI, notification of funding agencies or other external parties as required in accordance with their policies and application of such agencies' consequences.

13. Whenever Lawson identifies a SFI that was not disclosed in a timely fashion by an investigator or sub-recipient investigator or, for whatever reason, was not previously reviewed during an ongoing PHS Funded Research project, the Designated Official must conduct the review described in Sections [3](#), [4](#) and [6](#), and within 120 days Lawson shall complete a retrospective review of the Investigator's activities related to the PHS Funded Research project conducted during the non-compliance period to assess whether any bias occurred in the design, conduct, or reporting of such research.

13.1. Lawson must document a retrospective review incorporating the following minimum elements:

13.1.1. Project number,

13.1.2. Project title,

13.1.3. Principal Investigator or contact principal investigator if a multiple principal Investigator model is used,

13.1.4. Name of the Investigator with the FCOI,

13.1.5. Name of the entity with which the Investigator has a FCOI,

13.1.6. Reason(s) for the retrospective review,

13.1.7. Detailed methodology used for the retrospective review (e.g. methodology of the review process, composition of the review panel, documents reviewed),

13.1.8. Findings of the review, and

13.1.9. Conclusions of the review.

14. Based on the results of the retrospective review, if appropriate, the Designated Official shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward.

14.1. If bias is found, the Designated Official is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, at a minimum, the key elements cited in [Section 13](#) and a description of the impact of the bias on the project and Lawson's plan of action to eliminate or mitigate the effect of the bias, including, but not limited to:

14.1.1. Impact on the project,

14.1.2. Extent of harm done, including any qualitative and quantitative data to support any actual or future harm,

14.1.3. Analysis of whether the project is salvageable.

14.2. Thereafter, Lawson shall submit FCOI reports annually as specified in [Section 9](#).

15. In any case in which the PHS Awarding Component determines that a PHS Funded Research 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 PHS Regulations, the Investigator is required to disclose the FCOI in each public presentation of the results of the research and publish an addendum to previously published presentations.

16. Pursuant to the PHS Regulations, on the basis of the PHS Awarding Component's 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 project to such an extent that further corrective action is needed or that Lawson has not Managed the FCOI in accordance with this policy, the PHS Awarding Component or PHS may determine that issuance of a stop work order by the contracting officer or other enforcement action is necessary until the matter is resolved. Upon receipt of a stop work order, the recipient of such order must notify the Designated Official, who will forward such order to the Investigator and, if applicable the Sub-recipient(s). Lawson, the Investigator and the Sub-recipient(s) must comply with the terms of the stop work order. The PHS Awarding Component or PHS enforcement remedies may extend to legal action and/or debarment and suspension (for details see 45 C.F.R. 74.14, 74.62, 92.12 and 92.43).

## **DEFINITIONS**

**Designated Official** – The person(s) designated by Lawson, through the Integrated Vice President, Research, to oversee the solicitation and review of disclosures of Significant Financial Interests from each Investigator and any Senior/Key Personnel who are planning to participate in, or who are participating in PHS Funded Research. The Designated Official shall be the Manager, Research Approval and Contracts.

**Disclosure** – An investigator's disclosure of SFIs to Lawson.

**Financial Conflict of Interest (FCOI)** – An SFI that could directly and significantly affect the design, conduct, or reporting of PHS Funded Research.

**Financial Interest** – Anything of monetary value, whether or not the value is readily ascertainable.

**Institutional Responsibilities** – An investigator's professional responsibilities on behalf of Lawson and/or Western University, the responsibilities of the Investigator pursuant to the policies, procedures and rules of Lawson and/or Western University, and (as applicable) any other responsibilities outlined in the Investigator's job description, employment agreement or appointment letter with London Health Sciences Centre and/or St. Joseph's Health Care London, Lawson, and/or Western University. This includes, (as applicable), activities such as research, research consultation, teaching, professional practice, institutional committee memberships and service on panels such as Research Ethics Boards or Data and Safety Monitoring Boards.

**Investigator** – The project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of PHS Funded Research, or proposed for such funding, which may include, for example, collaborators or consultants. Investigator also includes senior/key personnel identified as such by Lawson in the grant application, progress report, or any other report submitted to the PHS Awarding Component by Lawson directly or as sub-recipient.

**Manage** – Taking action to address a FCOI, which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

**Public Health Service (PHS)** – The Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health.

**PHS Awarding Component** – The organizational unit of the PHS that funds research that is subject to the PHS Regulations or other funding entity requiring compliance with applicable PHS Regulations.

**PHS Funded Research** – Research funded by a PHS Awarding Component.

**PHS Regulations** – The US Regulations 42 C.F.R. Part 50 and 45 C.F.R. Part 94, as they may be amended from time to time.

**Senior/Key Personnel** – A project director or principal Investigator of a PHS Funded Research project and any other person identified as senior/key personnel in the grant application, progress report or any other report submitted to the PHS Awarding Component by Lawson.

**Significant Financial Interest (SFI)** (as defined in [Public Health Service \(PHS\) Regulations: Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought \(42 C.F.R. Part 50, Subpart F\)](#) –

A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities.

- With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g. consulting fees, honoraria, paid authorship), equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
- With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g. stock, stock option, or other ownership interest) or intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income related to such rights and interests.
- For the purposes of making a disclosure, investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e. that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities, provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, State or local government agency, a US institution of higher education, an academic teaching hospital, a medical centre, or a research institute that is affiliated with an institution of higher education. This disclosure will include, at a minimum; the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The Designated Official(s) will determine if further information is needed, including a determination or Disclosure of monetary value, in order to determine whether the travel constitutes a FCOI with the PHS funded research.

Exclusions: Significant Financial Interest does not include the following types of financial interests:

- Salary, royalties, or other remuneration paid by Lawson and/or Western University to the Investigator if the Investigator is currently employed or otherwise appointed by Lawson, including intellectual property rights assigned to Lawson and/or Western University and agreements to share in royalties related to such rights,
- Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles,
- Income from seminars, lectures, or teaching engagements sponsored by a Federal, State or local government agency, a US institution of higher education, an academic teaching hospital, a medical centre, or a research institute that is affiliated with an institution of higher education, or
- Income from service on advisory committees or review panels for a Federal, State or local government agency, a US institution of higher education, an academic teaching hospital, a medical centre, or a research institute that is affiliated with an institution of higher education.

**Sub-recipient** – A third party organization (sub-contractor or sub-awardee) that receives funding from a prime awardee to collaborate in carrying out an externally funded research project. Monies and responsibilities are passed down to a sub-recipient through a sub-award or sub-contract that outlines the scope of work, budget and laws and regulations that the sub-recipient must adhere to.

**Sub-recipient Investigator** – An investigator who is planning to participate in, or who is participating in any research funded by the Public Health Service through a sub-award or sub-contract between the prime awardee and a sub-recipient.

## REFERENCES

[Public Health Service \(PHS\) Regulations: Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought \(42 C.F.R. Part 50, Subpart F\)](#)  
[Other Applicable PHS Regulations](#)  
[List of Agencies Using the PHS Regulations Applicable to FCOI](#)

## APPENDICES

Appendix A – [Financial Interests Disclosure Report](#)