

FCOI in US PHS Funded Research (NIH, etc.) and other applicable sources

OVERVIEW

This Procedure, approved by the Provost and the Vice Principal (Research and International Relations), defines the compliance requirements for research conducted with funding from any agency of US Public Health Services (PHS), including [National Institutes of Health \(NIH\)](#), and any other research funding sources which have adopted [US PHS Financial Conflict of Interest \(FCOI\) Regulations](#) (42 C.F.R. Part 50 and 45 C.F.R. Part 94). In this Procedure, these various sources of research funding are collectively referred to as “PHS”.

In addition to compliance with all applicable University policies and procedures, including without limitation [Regulation on Conflict of Interest](#), [Regulation on the Conduct of Research](#), [Policy on Research Involving Human Participants](#), [Policy on the Study and Care of Animals](#), all Investigators, who are applying for and/or have been awarded PHS funding or who are participating in a PHS-funded research project, whether directly or through a subaward/subcontract, must comply with this Procedure.

PURPOSE

- To clarify the disclosure requirements regarding the reporting of Significant Financial Interests (SFI) by Investigators;
- To outline the process by which a Designated Official confirms whether the SFI is connected to an Investigator’s Institutional Responsibilities and assesses whether it is a Financial Conflict of Interest (FCOI) for a PHS-funded project;
- To set out the responsibility of the University for managing and reporting FCOIs to PHS, for informing Investigators of the FCOI Procedure, and for ensuring Subrecipient compliance;
- To promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under by PHS will be free from bias resulting from investigator FCOI

DEFINITIONS

Designated Official	person(s) designated by the University to oversee the solicitation and review disclosures of Significant Financial Interest (SFI) from each Investigator and any Senior/key personnel who are planning to participate in, or who are participating in PHS funded research.
Disclosure	an Investigator’s disclosure of SFIs to the University
Financial Conflict of Interest (FCOI)	a 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 the University, the responsibilities of the Investigator pursuant to the policies, procedures and rules of the University, and (as applicable) any other responsibilities outlined in the Investigator’s job description, employment agreement or appointment letter with the University. This includes, (as applicable), activities such as research, teaching, professional practice, institutional committee memberships and service on panels such as the Research Ethics Boards and others

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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 the University in the grant application, progress report, or any other report submitted to PHS by the University under this Procedure
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
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 (NIH)
PHS FCOI 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
Significant Financial Interest (SFI)	<p>a) 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:</p> <ul style="list-style-type: none"> • 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. <p>b) 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, an 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.</p> <p>The Designated Official(s) will determine if further information is needed, including a determination or Disclosure of monetary value, in order to assess whether the travel constitutes a FCOI with the PHS-funded research.</p>

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	<p>c) Exclusions: The term Significant Financial Interest does not include the following types of Financial Interests:</p> <ul style="list-style-type: none"> • salary, royalties, or other remuneration paid by the University to the Investigator if the Investigator is currently employed or otherwise appointed by the University, including intellectual property rights assigned to the 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, an 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, an institution of higher education, an academic teaching hospital, a medical centre, or a research institute that is affiliated with an institution of higher education.
<p>Subrecipient</p>	<p>a third party organization (subcontractor or subawardee) that receives funding from a prime awardee (i.e., McGill) to collaborate in carrying out an externally-funded research project. Monies and responsibilities are passed down to a Subrecipient through a subaward or subcontract that outlines the scope of work, budget and laws and regulations that the Subrecipient must adhere to</p>
<p>Subrecipient Investigator</p>	<p>an Investigator who is planning to participate in, or who is participating in any research funded by the PHS through a subaward or subcontract between the University and a Subrecipient</p>

PROCEDURE

1. REPORTING BY INVESTIGATORS
2. ASSESSMENT AND RECORD-KEEPING BY DESIGNATED OFFICIAL(S)
3. MANAGEMNET AND REPORTING OF FCOI
4. OTHER UNIVERSITY AND INVESTIGATOR RESPONSIBILITIES: TRAINING, SUBCONTRACTING AND PUBLIC ACCESSIBILITY OF INFORMATION
5. NON-COMPLIANCE CONSTITUTES MISCONDUCT

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1. REPORTING BY INVESTIGATORS

1.1. Who must disclose: all Investigators who are:

- applying for and/or receiving PHS funding, or
- who are working on a PHS funded research project

whether directly or through subcontract, must disclose, in writing to the Designated Official at the University, all SFIs that they, and their spouse and dependent children have, at the following times:

a. Initial disclosure:

- i. initial disclosure must be made before the time of application for PHS-funded research;
- ii. the initial disclosure must include all SFIs in the 12 months preceding the disclosure.

b. Ongoing disclosure:

- i. within 30 days of discovering or acquiring (including but not limited to a purchase, marriage, inheritance, etc.) a new SFI, and
- ii. 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.

c. New to the University:

All investigators who are new to the 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.

1.2. Steps to Disclose Significant Financial Interests (SFI) to the University

To disclose Significant Financial Interests to the University:

- a. the Investigator, and (as applicable) their spouse and dependent children must complete the appropriate Disclosure and Consent Form(s) for SFI and return it to the Designated Official(s).
- b. the Designated Official(s) will determine whether the third party entity(ies) or individual(s) named in the SFI disclosed by an Investigator (or spouse and/or dependent children), should be informed of the Disclosure and the fact that the disclosed information may be made available to the PHS or, in the case of a FCOI, to the public. The Designated Official(s) will provide the informed third party entity or individual with the opportunity to indicate any concern with such access to the SFI information and may obtain consent using the Informed Consent Form from Third Party for Disclosure of Personal Information.

2. ASSESSMENT AND RECORD-KEEPING BY DESIGNATED OFFICIAL(S)

2.1. The Designated Official(s) must review all disclosures of SFIs from Investigators, including Subrecipient Investigators, within the timeframes noted below in 2.2., and determine whether:

- a) the disclosures relate to PHS funding; and
 - an investigator's SFI is related to PHS research when the Designated Official (s) reasonably determine that the SFI:
 - could be affected by the PHS-funded research; or
 - is an entity whose financial interest could be affected by the research.

The Designated Official(s) may involve the Investigator in the Designated Official's determination of whether a SFI is related to the PHS-funded research.

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b) whether each SFI is a FCOI.

- a FCOI exists when the University, through its Designated Official, reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

2.2. The review and determination noted in 2.1. above must be conducted by the Designated Official(s) at the following times:

- prior to the University's expenditure of any funds under a PHS-funded research project;
- within sixty (60) days whenever, in the course of an ongoing PHS-funded project, an Investigator or Subrecipient Investigator, who is a new participant in the project, discloses a SFI or an existing Investigator or Subrecipient Investigator discloses a new SFI to the University; and
- within sixty (60) days whenever the University identifies a SFI that:
 - was not disclosed in a timely manner by an Investigator or Subrecipient Investigator; or
 - for whatever reason, was not previously reviewed by the University during an ongoing PHS-funded research project.

2.3. Record-keeping: The Designated Official(s), on behalf of the University, must maintain records relating to all Investigator Disclosures of SFIs and the University's review of, and response to, such disclosures (whether or not a disclosure resulted in the University's determination of a FCOI) and all actions under the University's policy or retrospective review related to the SFI and/or FCOI, if applicable, for at least three (3) years from the date the final expenditures report is submitted to PHS, the date of final payment or, where applicable, for other time periods specified.

3. MANAGEMENT AND REPORTING OF FCOI

3.1. If the Designated Official(s) determine through their review pursuant to 2.1. above that there is a FCOI, the Designated Official(s) must prepare a FCOI management plan to manage the FCOI. Key elements of the management plan include:

- role and principal duties of the conflicted Investigator in the research project;
- conditions of the management plan;
- how the management plan is designed to safeguard objectivity in the research project;
- confirmation of the Investigator's agreement to the management plan;
- how the management plan will be monitored to ensure Investigator compliance; and

The Designated Official(s) may include additional elements into any management plan that ensure that the FCOI is properly Managed.

Examples of conditions or restrictions that might be imposed to Manage a FCOI:

- public disclosure of FCOI (e.g., when presenting or publishing research);
- for research projects involving humans, disclosure of FCOI directly to the participants;
- 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;
- modification of the research plan;
- change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- reduction or elimination of the financial interest (e.g., sale of an equity interest), or
- severance of relationships that create FCOI.

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- 3.2. The Investigator is required to comply with the management plan prescribed by the Designated Official(s).
- 3.3. On behalf of the University, the Designated Official must monitor compliance with the management plan on an ongoing basis until the completion of the project.
- 3.4. Reporting requirements to PHS: The University, through its Designated Official, must provide initial and ongoing FCOI reports to PHS as applicable:
 - a) after the award is granted but prior to the University's expenditure of any funds under a PHS-funded research project;
 - b) annually at the same time as the annual progress report is due:

For any FCOI previously reported by the University, 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.
 - c) in the time and manner specified by PHS for any other FCOI reports for the duration of project period (including extensions with or without funds).
 - d) Subrecipients: The University must provide FCOI reports to PHS regarding all FCOIs of all Subrecipient Investigators prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

FCOI reports by the University must include sufficient information to enable PHS to understand the nature and extent of the financial conflict, and to assess the appropriateness of the University's management plan. Each FCOI report prepared by the Designated Official on behalf of the University must contain:

- grant number;
- project director/principal investigator or contact project director/principal investigator if a multiple project director/principal investigator model is used;
- name of Investigator with the FCOI;
- name of the entity with which the Investigator has a FCOI;
- nature of FCOI (e.g., equity, consulting fees, travel reimbursement, honoraria);
- value of the financial interest per year:
 - \$0-\$4,999;
 - \$5,000-\$9,999;
 - \$10,000-\$19,999;
 - amounts between \$20,000-\$100,000 by increments of \$20,000;
 - amounts above \$100,000 by increments of \$50,000; or
 - a statement that a value cannot be readily determined
- a description of how the financial interest relates to PHS-funded research and the basis for the University's determination that the financial interest conflicts with such research; and
- key elements of the University's management plan.

4. OTHER UNIVERSITY AND INVESTIGATOR RESPONSIBILITIES: TRAINING, SUBCONTRACTING AND PUBLIC ACCESSIBILITY OF INFORMATION

4.1. Training: The University provides training with respect to the requirement of this Procedure, the Investigator's responsibilities regarding the disclosure of SFIs and the PHS regulations. The mandatory training consists of the completion of the NIH Tutorial found at:

<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>

Each Investigator must complete the Training as follows:

- prior to engaging in PHS-funded research,
- at least every four years, and
- immediately when any of the following circumstances apply:
 - the University revises its financial conflict of interest policies
 - an Investigator is new to the University
 - the University finds that an Investigator is not in compliance with the University's financial conflict of interest policy or management plan.

4.2. Subcontracting

If the University carries out the PHS-funded research through a Subrecipient, the University must take reasonable steps to ensure that any Subrecipient Investigator complies with this Procedure:

- a) incorporate as part of written agreement with Subrecipient, terms that establish whether this Procedure or the Subrecipient's policy will apply to the Subrecipient's Investigators.
- b) if the Subrecipient's Investigators must comply with the Subrecipient's financial conflicts of interest policy, the University shall obtain from the Subrecipient a certification that its policy complies with the PHS Regulations
- c) if the Subrecipient's Investigators must comply with this Procedure, the University must obtain a written agreement specifying time periods for the Subrecipient to submit all Investigator disclosures of SFIs to the University. Such time periods shall be sufficient to enable the University to comply in a timely fashion with its review, management and reporting obligations under this procedure.

4.3. Public Accessibility of Information

- a) the University shall maintain an up-to-date, written, enforced policy (and associated procedures) on financial conflicts of interest, that complies with PHS regulations and make such policy available via a publicly accessible website.
- b) after an award has been granted, but prior to the University's expenditure of any funds under a PHS-funded research project, the University shall make available, via a publicly accessible website the information listed in 4.3.c. concerning any SFI that meets the following criteria:
 - SFI was disclosed and is still held by the investigator who has been identified by the University as senior/key personnel for the NIH-funded research project in the grant application, contract proposal, contract, progress report, or other required report submitted to the NIH;
 - the University determines that the SFI is related to the NIH-funded research; and
 - the University determines that the SFI is a FCOI.

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- c) the University must post on the publicly accessible website or make available in response to written requests the following minimum information:
- investigator's name,
 - investigator's position with respect to the research project,
 - nature of the SFI,
 - approximate dollar value of the SFI:
 - \$0-\$4,999;
 - \$5,000-\$9,999;
 - \$10,000-\$19,999;
 - amounts between \$20,000-\$100,000 by increments of \$20,000;
 - amounts above \$100,000 by increments of \$50,000 or
 - a statement that a value cannot be readily determined;
 - the entity with which the investigator has a FCOI, to enhance transparency and accountability.
- d) the University shall update the above-noted information within 60 days when there are changes to the information and, at a minimum, shall update the above-noted information annually.
- e) the above-noted information, as updated, shall remain available for responses to written requests or for posting via the University's publicly accessible website for at least three (3) years from the date that the information was most recently updated.

5. NON-COMPLIANCE CONSTITUTES MISCONDUCT

- a. Non-compliance constitutes misconduct. In the event of non-compliance, the University may initiate actions under applicable collective and other agreements or University Policy.
- b. Retrospective Review and Mitigation: Whenever the University identifies a SFI that was not disclosed in a timely fashion by an Investigator or, for whatever reason, was not previously reviewed by the institution during an ongoing PHS-funded project (including but not limited to when the SFI was not reviewed in a timely fashion or reported by a Subrecipient):

Step 1: the designated official shall, within sixty (60) days determine whether:

- the disclosures relate to PHS funding; and
 - 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 an entity whose financial interest could be affected by the research.

The Designated Official may involve the Investigator in the Designated Official's determination of whether a SFI is related to the PHS-funded research.

- each SFI is a FCOI.
 - a FCOI exists when the University, through its Designated Official, reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

Step 2: If the Designated Official determines that a FCOI exists, the Designated Official must implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such FCOI going forward.

Step 3: Within 120 days of the University's determination of non-compliance, the University shall complete a retrospective review of the Investigator's activities and the PHS-funded project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the non-compliance, was biased in the design, conduct, or reporting of such research.

Step 4: The University is required to document the retrospective review; such documentation shall include, but not necessarily be limited to, all of the following key elements:

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- project number;
- project title;
- principal investigator or contact principal investigator if a multiple principal investigator model is used;
- name of the Investigator with the FCOI;
- name of the entity with which the Investigator has a FCOI;
- reason(s) for the retrospective review;
- detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- findings of the review; and
- conclusions of the review.

Step 5: Based on the results of the retrospective review, if appropriate, the University shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, the University is required to notify PHS promptly and submit a mitigation report to PHS. The mitigation report must include, at a minimum, the key elements cited in Step 4 above and a description of the impact of the bias on the project and the University's plan of action or actions taken to eliminate or mitigate the effect of the bias (including, but not limited to: impact on the project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the project is salvageable).

The University will, thereafter, submit FCOI reports annually as specified in Part 3 of this Procedure.

- c. In any case in which the PHS 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 a FCOI that was not managed or reported by the University as required by the regulations, the University must not only require the Investigator involved to disclose the FCOI in each public presentation of the results of the research, but also to request an addendum to previously published presentations.
- d. Pursuant to US Regulations, on the basis of its review of records or other information that may be available, PHS may decide that a particular FCOI will bias the objectivity of the PHS-funded project to such an extent that further corrective action is needed or that the University has not managed the FCOI in accordance with this procedure, the 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.