

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

1. INTRODUCTION

This Procedure is an adaptation of the McGill “FCOI in US PHS Funded Research (NIH, etc.) and other applicable sources”.

It 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).

This Procedure complies with the *Règlements sur les conflits d'intérêts* (Conflict of interest regulations) and the *Politique relative au statut de chercheur et aux privilèges de recherche* (Policy on researcher status and research privileges) of the CIUSSS de l'Ouest-de-l'Île-de-Montréal.

All Investigators must comply with this Procedure if they are applying for and/or have been awarded PHS funding or are participating in a PHS-funded research project, whether directly or through a subaward/subcontract.

2. DEFINITIONS AND ACRONYMS

Designated Official: Person designated by the Institution (see below) 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 Institution.

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.

Institution: Douglas Research Centre.

Institutional Responsibilities: An Investigator's professional responsibilities on behalf of the Institution, the responsibilities of the Investigator pursuant to the policies, procedures, and rules of the Institution, and (as applicable) any other responsibilities outlined in the Investigator's job description, employment agreement or appointment letter with the Institution. 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.

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 in the grant application, progress report, or any other report submitted to PHS by the Institution under this Procedure.

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): A Financial Interest consisting of one or more of the 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 described in the section 5.1 of the current procedure.

Subrecipient: A third party organization (subcontractor or subawardee) that receives funding from a prime awardee of PHS funds 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.

Subrecipient Investigator: 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 Institution and a Subrecipient.

3. OBJECTIVES

The objectives of this procedure are:

- 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 Institution 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.

4. AREAS OF APPLICATIONS

4.1. Who Must Disclose their Financial Interests and When

Investigators who are:

- Applying for and/or receiving PHS funding; or
- Working on a PHS funded research project;

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

- Initial disclosure:

- Initial disclosure must be made before the time of application for PHS-funded research;
- The initial disclosure must include all SFIs in the 12 months preceding the disclosure;
- Ongoing disclosure:
 - Within 30 days of discovering or acquiring (including but not limited to a purchase, marriage, inheritance, etc.) a new SFI; and
 - 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.

All investigators who are new to the Institution 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.

Terms that establish whether this Procedure or the Subrecipient's policy or procedure will apply to the Subrecipient's Investigators must be determined and incorporated as part of written agreement with the Subrecipient's Investigator.

4.2. What Must be Disclosed

Significant Financial Interest (SFI): A Financial Interest is significant and must be disclosed when it consists of one or more of the following interests of the Investigator (and those of the Investigator's spouse and children) that reasonably appears to be related to the Investigator's Institutional Responsibilities:

- With regard to any publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the twelve (12) months preceding the Disclosure and the value of any equity interest in the entity as of the date of Disclosure exceeds US\$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 SFI exists if the value of any remuneration received from the entity in the twelve (12) months preceding the Disclosure exceeds US\$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 US Federal, State or local government agency, a US institution of higher education, or an academic teaching hospital, a medical centre, or a research institute that is affiliated with a US 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 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.

4.3. Financial Interests Excluded

Exclusions: The term SFI does not include the following types of Financial Interests:

- Salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution 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 US Federal, State or local government agency, a US institution of higher education, or an academic teaching hospital, a medical centre, or a research institute that is affiliated with a US institution of higher education;
- Medical earnings from an incorporated medical practice; or
- Income from service on advisory committees or review panels for a US Federal, State or local government agency, a US institution of higher education, or an academic teaching hospital, a medical centre, or a research institute that is affiliated with a US institution of higher education.

5. ROLES AND RESPONSABILITIES

5.1. Investigator

The Investigator must comply with the current procedure and management plan prescribed by the Designated Official.

He/she must undergo a mandatory training consisting of the completion of the NIH Tutorial found at: <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm> and 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 Institution revises its financial conflict of interest Procedure;
 - An Investigator is new to the Institution;
 - The Institution finds that an Investigator is not in compliance with the Institution's financial conflict of interest Procedure or management plan.

5.2 Institution and Designated Official

On behalf of the Institution, the Designated Official must review all SFI disclosures and FCOI and monitor compliance with the management plan on an ongoing basis until the completion of the project.

The Institution, through its Designated Official, must provide initial and ongoing FCOI reports to PHS as applicable. It also provides training with respect to the requirement of this Procedure, the Investigator's responsibilities regarding the disclosure of SFIs and the PHS regulations.

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

5.3. Subrecipient

The Institution shall obtain from the Subrecipient a certification that its policy complies with the PHS Regulations

The Institution must obtain a written agreement specifying time periods for the Subrecipient to submit all Investigator disclosures of SFIs to the Institution. Such time periods shall be sufficient to enable the Institution to comply in a timely fashion with its review, management and reporting obligations under this procedure.

6. OPERATING PROCEDURES

6.1 Reporting by Investigators

To disclose SFIs to the Institution:

- The Investigator must complete the appropriate Disclosure and Consent Form for SFI and return it to the Designated Official;
- The Designated Official will determine whether the third party entity(ies) or individual(s) named in the SFI disclosed by an Investigator, 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 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.

6.2 Assessment and Record-Keeping by the Designated Official

6.2.1. Review of the Disclosure by the Designated Official

The Designated Official must review all disclosures of SFIs from Investigators, including Subrecipient Investigators, within the time frames noted below in 6.2.2, and determine whether:

- The disclosures relate to PHS funding;
 - An investigator's SFI is related to PHS research when the Designated Official 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 may involve the Investigator in the Designated Official's determination of whether a SFI is related to the PHS-funded research.

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

6.2.2. Time Frames of the Review

The review and determination noted in 6.2.1 above must be conducted by the Designated Official at the following times:

- Prior to the Institution'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 Institution;
- Within sixty (60) days whenever the Institution 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 Institution during an ongoing PHS-funded research project.

6.2.3. Record-Keeping

The Designated Official, on behalf of the Institution, must maintain records relating to all Investigator Disclosures of SFIs and the Institution's review of, and response to, such disclosures (whether or not a disclosure resulted in the Institution's determination of a FCOI) and all actions under the Institution's current Procedure, if applicable, for at least three (3) years.

6.3. Management and Reporting of FCOI

6.3.1. Management Plan

If the Designated Official determine through their review pursuant to 6.2.1 above that there is a FCOI, the Designated Official must prepare a FCOI management plan. 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 safe guard 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 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.

6.3.2. Reporting Requirements to PHS

The Institution, through its Designated Official, must provide initial and ongoing FCOI reports to PHS as applicable:

- After the award is granted but prior to the Institution's expenditure of any funds under a PHS-funded research project;

- Annually at the same time as the annual progress report is due. For any FCOI previously reported by the Institution, 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.
- 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).
- Subrecipients: The Institution 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 Institution must include sufficient information to enable PHS to understand the nature and extent of the financial conflict, and to assess the appropriateness of the Institution's management plan. Each FCOI report prepared by the Designated Official on behalf of the Institution must contain:

- Grant number;
- Project director/principal investigator;
- 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:
 - US\$0 - US\$4,999;
 - US\$5,000 - US\$9,999;
 - US\$10,000-US\$19,999;
 - Amounts between US\$20,000 - US\$100,000 by increments of US\$20,000;
 - Amounts above US\$100,000 by increments of US\$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 Institution's determination that the financial interest conflicts with such research; and
- Key elements of the Institution's management plan.

6.4. Public Accessibility of Information

6.4.1. Public Availability of the Procedure

The Institution 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.

6.4.2. Public availability of the SFI disclosures and FCOIs

After an award has been granted, but prior to the Institution's expenditure of any funds under a PHS-funded research project, the Institution shall make available, via a publicly accessible website the information listed in 6.4.3 concerning any SFI that meets the following criteria:

- SFI was disclosed and is still held by the investigator who has been identified by the Institution as senior/key personnel for the PHS-funded research project in the grant application, contract proposal, contract, progress report, or other required report submitted to the PHS;
- The Institution determines that the SFI is related to the PHS-funded research; and

- The Institution determines that the SFI is a FCOI.

6.4.3. Posted information

The Institution 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:
 - US\$0 - US\$4,999;
 - US\$5,000 - US\$9,999;
 - US\$10,000 - US\$19,999;
 - Amounts between US\$20,000 - US\$100,000 by increments of US\$20,000;
 - Amounts above US\$100,000 by increments of US\$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.

The Institution 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.

The above-noted information, as updated, shall remain available for responses to written requests or for posting via the Institution's publicly accessible website for at least three (3) years from the date that the information was most recently updated.

6.5. Non-compliance constitutes misconduct

Non-compliance constitutes misconduct. In the event of non-compliance, the Institution may initiate actions under the Institution's Responsible Conduct Policy.

6.5.1. Retrospective Review and Mitigation

Whenever the Institution 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):

6.5.1.1. *Step 1:* The Designated Official shall, within sixty (60) days, review the Disclosure according to the conditions stated at 6.2.1.

6.5.1.2. *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.

6.5.1.3. *Step 3:* Within 120 days of the Institution's determination of non-compliance, the Institution 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.

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

- 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.

6.5.1.5. *Step 5:* Based on the results of the retrospective review, if appropriate, the Institution 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 Institution 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 Institution'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 Institution will, thereafter, submit FCOI reports annually.

6.5.2. *Retroactive disclosure of the FCOI*

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 Institution as required by the regulations, the Institution 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 and publications.

6.5.3. *Enforcement action*

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 Institution 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.