



FINANCIAL CONFLICTS OF INTEREST (FCOI) COMPLIANCE GUIDELINES FOR US PUBLIC HEALTH SERVICE (PHS) AGENCIES

Summary

Brock University's ("Institution") Institutional FCOI Procedure defines the compliance requirements for conducting research with funding from United States ("US") Public Health Services ("PHS") agencies such as but not limited to, the National Institutes of Health ("NIH"), and other research funding sources which have implemented FCOI Regulations. Throughout the Institutional FCOI Procedure, the sources of research funding from an agency of US Public Health Services are collectively referred to as "PHS".

Scope

All Investigators who are applying for and/or have been awarded PHS funding or those investigators who are directly participating in a PHS-funded research project or otherwise participating in such research through a subaward/subcontract must comply with the Institutional FCOI Procedure.

Objectives

The purpose of the Institutional FCOI Procedure is to ensure that any funding received from PHS is free from any bias resulting from FCOI, and in particular, to provide guidance about:

- the disclosure requirements for Investigators regarding reporting of significant financial interests ("SFI");
- the process by which Brock's Designated Official may determine whether the SFI has any connection to the Investigator's responsibilities to Brock and assesses whether it is a FCOI for a PHS funded project; and
- the Institution's obligations for managing and reporting FCOIs to PHS agencies, informing Investigators of the FCOI Procedure, and to ensure compliance by Investigators and Subrecipients.

Definitions

Designated Official means person(s) designated by the Institution to oversee reporting and the reviewing of disclosures of SFI from each Investigator and any researcher who are involved research funded by a PHS agency. The Designated Official may be contacted at orslegal@brocku.ca

Disclosure means an Investigator's disclosure of SFIs to the Institution.

Financial Conflict of Interest (FCOI) means Significant Financial Interest that could directly and significantly affect the design, conduct or reporting of PHS-funded research.

Financial Conflict of Interest Regulations (FCOI Regulations) means US PHS Financial Conflict of Interest Regulations 42 C.F.R. Part 50 and 45 C.F.R. Part 94.

Financial Interest means 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), irrespective of whether 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.

Institutional Responsibilities means 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 means 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 essential to the research or identified by the Institution in the grant application, progress report, or any other report submitted to PHS by the Institution.

Manage means 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) means 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).

Senior/Key Personnel means the principal Investigator or project director, and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution under the Regulations (or, in the case of a research contract for the US government, any other person identified as senior/key personnel in the contract proposal and contract).

Significant Financial Interest (SFI) means

(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:

(i) 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;

(ii) 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

(iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(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 as defined at 20 U.S.C. 1001(a) (domestic or foreign), an academic teaching hospital, a medical center, 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 an FCOI with the PHS-funded research.

(c) The term *significant financial interest* 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; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; 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 as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, 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 as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.”

Subrecipient means a third-party organization (subcontractor or subawardee) that receives funding from a primary awardee at Institution 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 means 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.

Training for Investigators

Institution shall make this Institutional FCOI Procedure available via a publicly accessible website or upon request. In addition, Institution shall inform each Investigator of this Institutional FCOI Procedure and require each Investigator to complete training regarding this Procedure, the Investigator’s responsibilities, and the FCOI Regulations.

Investigators must familiarize themselves with this Institutional FCOI Procedure and signify in a manner as required by the Institution that they have read and understood it and agree to comply with it before engaging in any PHS funded research, and must do so again at least every 4 years.

Investigators must also complete the [NIH on-line tutorial](#) for the FCOI Regulation regarding grants before engaging in any PHS funded research and must do so again at least every 4 years. When the NIH tutorial

is completed, Investigators must save a copy of the certificate that is generated and forward it to the appropriate Designated Official to ensure that the Institution has a record of Investigators who have completed the training.

Investigators must complete the aforementioned training:

- prior to engaging in PHS-funded research;
- once every four years; and
- when the following circumstances apply:
 - the Institution revises its FCOI Procedure in a way that affects the obligations and/or rights of Investigators;
 - an Investigator is new to the Institution; or
 - the Institution finds that an Investigator is not in compliance with the Institution's FCOI Procedure or management plan.

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

Investigator Reporting Requirements

All Investigators who are applying for and/or receiving PHS funding or Investigators who are participating in PHS funded research, directly or as a recipient of a sub-award, must disclose in writing the Significant Financial Interest status of themselves, their spouse, and dependent children to the Designated Official of the Institution:

- no later than at the time of submission of an application PHS funding for research;
- at least annually during the period of a PHS award; and
- within 30 days of discovering or acquiring a new SFI.

Investigators who are new to the Institution and are transferring PHS funding to the Institution must disclose their SFI status before such PHS funds can be dispersed.

To disclose SFIs to the Institution, the Investigator, on behalf of his/her self, and (if applicable) their spouse and dependent children must complete the appropriate Disclosure and Consent Form(s) for SFIs and return them to the Designated Official. The Designated Official will determine whether the third-party entity/individual 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 entity/individual in which the Investigator, his/her spouse or his/her dependent child has a SFI must complete the Informed Consent by Third Parties for Disclosure of Personal Information Form. The entity must return that Consent Form to the Investigator, who must return the Consent Form to the Designated Official.

SFI Review Process

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

- The disclosed SFI(s) relate to PHS funding (an investigator's SFI is related to PHS research when the Designated Official reasonably determines that the SFI could be affected by the PHS

funded research or when the SFI is an entity whose financial interest could be affected by the research); and

- For each SFI that is found to be related to PHS funded research, determine if an FCOI exists.

The Designated Official will assess the declared SFI and determine whether there is an FCOI. If the Designated Official determines that there is an FCOI, a management plan will be developed and implemented prior to releasing the PHS funds. The Designated Official may seek additional information from the Investigator at any stage of the aforementioned process.

The Designated Official(s) must conduct the review and determination of all disclosures of SFIs 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; and
- 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.

FCOI Management

If the Designated Official determines through the review process that there is a FCOI, the Designated Official must prepare a FCOI management plan to Manage the FCOI. The management plan must include the following key elements:

- 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 conflicted Investigator's agreement to the management plan; and
- how the management plan will be monitored to ensure Investigator compliance.

The Designated Official may include additional elements in any management plan to ensure the FCOI is appropriately Managed. Conditions or restrictions imposed to Manage a FCOI may include:

- 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.

If a SFI is disclosed during an ongoing research project, interim measures may be imposed, as necessary, regarding the Investigator's participation in the research project pending completion of the FCOI review.

The Investigator is required to comply with the management plan prescribed by the Designated Official.

On behalf of the Institution, the Designated Official must monitor compliance with the management plan on an ongoing basis until the completion of the project.

PHS Reporting Requirements

The Institution, through the Designated Official, must provide initial, ongoing and revised FCOI reports to PHS as follows (as applicable):

- after the award is granted but prior to the Institution's expenditure of any funds under an PHS funded research project; and
- at least annually, thereafter.
- All reports must be submitted in the time and manner specified by PHS for the duration of the project period (including extensions with or without funds). In the case of the NIH, such annual reports must be submitted at the same time as when the grantee is required to submit the NIH annual progress report, or multi-year progress report or at the time of extension.
- 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.
- Subrecipients: The Institution must provide FCOI reports to the PHS awarding component 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 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 the PHS funded research and the basis for the Institution's determination that the Financial Interest conflicts with such research; and
- key elements of the FCOI management plan.

Maintenance of Records

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 this process related to the SFI and/or FCOI for at least three (3) years from the date the final expenditures report is submitted to the PHS agency, the date of final payment or, where applicable, for other time periods specified in 45 CFR 75.361.

Noncompliance

If an Investigator's failure to comply with this Guideline or a management plan appears to have biased the design, conduct or reporting of any PHS funded research, the Institution, through the Designated Official, shall promptly notify the PHS agency of the corrective action taken or to be taken.

In the event of non-compliance with this Guideline, the Institution may initiate actions under applicable collective and other agreements or Institution policy and procedures, which may result in discipline or other administrative actions necessary to ensure compliance with this Guidelines.

Retrospective Review and Mitigation

- A. 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 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):
1. The Designated Official shall, within sixty (60) days determine whether the Disclosure relate to the PHS funding and determine whether a FCOI exists:
 - i. An Investigator's SFI is related to PHS funded research when the Designated Official reasonably determines that the SFI:
 - a. could be affected by the PHS funded research; or
 - b. is an entity whose financial interest could be affected by the research.
 - ii. The Designated Official may involve the Investigator in the Designated Official's determination of whether a SFI is related to the PHS funded research.
 - iii. The Designated Official's determination that a SFI is a FCOI is final.
 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 the FCOI going forward.
- B. Whenever an FCOI is not identified or managed in a timely manner (including when (a) an Investigator fails to disclose a SFI that is determined by Institution to constitute a FCOI; (b) Institution fails to review or manage an FCOI; or (c) Investigator fails to comply with a FCOI managed plan)
1. Within 120 days of the Institution's determination of noncompliance, 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 noncompliance, was biased in the design, conduct, or reporting of such research.
 2. 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;
 - nature and value of the SFI;
 - 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.
3. 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.
 4. If bias is found, the Designated Official is required to notify the PHS agency and submit a mitigation report to PHS. The mitigation report must include, at a minimum, the key elements cited in Step 4 above and (1) 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); and (2) the Institution will, thereafter, submit FCOI reports annually as specified in these Procedures.
 5. 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 an FCOI that was not Managed or reported by the Institution as required by the PHS Regulations, the Investigator is not only required to disclose the FCOI in each public presentation of the results of the research, but publish an addendum to previously published presentations.
 6. Pursuant to the US Regulations, on the basis of its review of records or other information that may be available, the 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 these Procedures, 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. Upon receipt of a Stop Work Order, the recipient of such order must notify the Office of Research Services, who will forward such order to the Investigator and, if applicable the Subrecipient(s). The Institution, the Investigator and the Subrecipient must comply with the terms of the Stop Work Order.

Subcontracting

If the Institution proposes to carry out the PHS funded research through a Subrecipient, the Institution through the Office of Research Services must include terms in the written agreement with the Subrecipient that establish whether the Institution's Procedure or the Subrecipient's FCOI policy will apply to the Subrecipient's Investigators.

If the Subrecipient's Investigators must comply with the Subrecipient's FCOI policy, the Institution shall obtain from the Subrecipient a certification that its policy complies with the PHS Regulations and the agreement with the Subrecipient shall specify the time period(s) for the Subrecipient to report all identified financial conflicts of interest to the awardee Institution. Such time period(s) shall be sufficient to enable the awardee Institution to provide timely FCOI reports, as required by the FCOI Regulations.

If the Subrecipient's Investigators must comply with this Procedure, Institution, through the Office of Research Services must obtain a written agreement specifying that the Subrecipient's Investigators must comply with this Procedure, and the time periods for each Subrecipient to submit all Investigator Disclosures of SFIs to the Institution. Such time periods shall be sufficient to enable the Institution, through the Designated Official to complete in a timely fashion its review, management and reporting obligations under this Procedure.

Accessibility of FCOI Information to the Public

The Institution, through the Office of Research Services, shall maintain an up-to-date version of this Procedure on its publicly accessible website.

After an award has been granted, but prior to the Institution's expenditure of any funds under a PHS funded research project, the Institution, through the Office of Research Services shall make available, via a publicly accessible website, the information 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, contact proposal, contract, progress report, or other required report submitted to the PHS;
- the Institution through the Designated Official determines that the SFI is related to PHS funded research; and
- the Institution, through the Designated Official determines that the SFI is a FCOI.

The Institution must post on the publicly accessible website 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; and
- the entity with which the Investigator has a FCOI.

The Designated Official 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 posting via the Office of Research Services publicly accessible website for at least three (3) years from the date that the information was most recently updated.

Additional Information

Brock Information, Guidelines and Policies:

1. [Policies](#)
2. [Office of Research Ethics](#)

US Regulations:

1. [42 CFR Part 50](#)
2. [45 CFR Part 94](#)