

Disclosure of Financial Conflicts of Interest: US Public Health Services Funding, Guideline for

1. Purpose

The purpose of this guideline is to ensure that University researchers who hold funding provided by agencies of the United States Department of Health and Human Services (DHHS) are compliant with requirements for disclosure of financial conflicts of interest stipulated by US DHSS funding agencies.

2. Scope

This guideline applies to researchers who currently hold, or intend to hold, funding directly or indirectly provided by agencies of the United States Department of Health and Human Services (DHHS), including Public Health Services (PHS).

3. Definitions

In this guideline:

- a) "Family" means an Investigator's spouse or domestic partner and dependent children or dependent children of his or her domestic partner.
- b) "FCOI Review Committee" means the committee created by the University for the conclusive determination of the existence of a Financial Conflict of Interest and with authority to impose conditions on an Investigator for management of that conflict of interest.
- c) "Financial Conflict of Interest" means a Significant Financial Interest which is determined by the FCOI Review Committee to be sufficiently tied to the Institutional Responsibilities of an Investigator so as to constitute a conflict of interest.
- d) "Financial Interest Disclosure Form" means the Form attached to this Procedure, or any on-line version of this form, as may be amended from time to time.
- e) "Institutional Responsibilities" means all research, teaching, professional practice, institutional committee memberships, service on panels and consulting activities of an Investigator.
- f) "Investigator" means the principal investigator and any other person who is responsible for the design, conduct, or reporting of Research funded by, or proposed for funding by, a PHS Awarding Component.
- g) "PHS Awarding Component" means the organizational unit of the PHS providing Research funding that is subject to this Procedure.
- h) "Research" means a systematic investigation designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research and product development.
- i) "Research Services Office" means that person or persons within the Research Services Office designated to accept the submission of a Financial Interest Disclosure Form on behalf of the University.
- j) "Significant Financial Interest" means anything of monetary value (whether or not the value is readily ascertainable) held by Investigator or Family and related to Institutional Responsibilities of Investigator, including but not limited to, salary or other payments for services (e.g. consulting fees, honoraria or paid authorship); equity interests (e.g.

stocks, stock options, or other ownership interest); and intellectual property rights (e.g. patents, copyrights and royalties from such rights).

- k) "Sponsored Travel" means any reimbursed or sponsored travel which is paid on behalf of the Investigator or his or her Family or reimbursed to the Investigator or his or her Family and which is related to the Investigator's Institutional Responsibilities.

4. Disclosure

- 4.1.** Investigators must disclose to the University any current Significant Financial Interest, or any Significant Financial Interest expected within the next 12 months, using the Financial Interest Disclosure Form.
- 4.2.** Disclosure of Significant Financial Interests is not required when that financial interest consists of:
- a) Salary, royalties, or other remuneration paid by the University in the context of current employment;
 - b) 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;
 - c) Income from seminars, lectures, teaching engagements or service on advisory committees or review panels for a federal, provincial or municipal government agency, institute of higher education (including affiliated research institute) or hospital.
- 4.3.** Investigators must also disclose to the University any Sponsored Travel using the Financial Interest Disclosure Form subject to the following guidelines:
- a) Disclosure must include details on the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration of the trip.
 - b) Disclosure is not required when the Sponsored Travel is reimbursed or sponsored by a federal, provincial or municipal government agency, an institution of higher education (including affiliated research institute) or a hospital.
- 4.4.** Principal Investigators have an obligation to identify each other person who may qualify as an Investigator under this Procedure in respect of a PHS award, and to request those Investigators to submit a Financial Interest Disclosure Form and provide the Research Services Office with a list of those Investigators.

5. Submission of Form

- 5.1.** Investigators must submit Financial Interest Disclosure Forms at the following times:
- a) At the time of any application for PHS funding, whether directly from PHS or through another institution as a sub-award;
 - b) One year following the previous financial interest disclosure within the term of an existing grant or sub-award;
 - c) Within thirty (30) days of a change in status of the terms and conditions of the PHS grant or sub-award;
 - d) Within thirty (30) days of any new Significant Financial Interest or change in status of any Investigator's financial interests within the term of an existing grant or sub-award;
 - e) Within thirty (30) days of any Sponsored Travel within the term of an existing grant or sub-award;
 - f) In response to any request by the Research Services Office within the term of an existing grant or sub-award.
- 5.2.** Investigators must submit the Financial Interest Disclosure Form online or as a separate document to the Research Services Office. If there is nothing to indicate the existence of a Significant Financial Interest, the form will be filed without further review. If there is an indication on the Form that a Significant Financial Interest is being disclosed, then the Research Services Office will immediately forward the Form to the Chairperson of the FCOI Review Committee for further review.

- 5.3. Where an Investigator intends to receive PHS Funding by way of a sub-award, the University may be required to submit the Financial Interest Disclosure Form to the institution making the sub-award for review and assessment of potential conflict of interest by that institution.
- 5.4. In instances where the disclosed Significant Financial Interest is less than \$10,000 and the potential conflict of interest can be easily managed or eliminated, the Chair of the FCOI Review Committee and the Research Services Office may elect to conduct an expedited review and render a decision. These actions shall be reported by the Chair to the FCOI Review Committee on a regular basis.

6. FCOI Review Committee

- 6.1. The FCOI Review Committee will review all disclosures of Significant Financial Interests forwarded by the Research Services Office to determine whether any Significant Financial Interests relate to PHS-funded research and determine whether a Financial Conflict of Interest exists. If a Financial Conflict of Interest is determined to exist, the Committee will, in consultation with the Principal Investigator, develop and implement a management plan that specifies the actions to be taken to manage or eliminate such Financial Conflict of Interest.
- 6.2. The FCOI Review Committee will be comprised of at least one faculty member from each Faculty with a record of receiving PHS funding, an Associate Vice-President (Research) or delegate and a representative from the Research Services Office. Faculty members will be appointed by their Deans for three-year terms.
- 6.3. All members of the FCOI Review Committee have an obligation to act with the highest level of integrity and to safeguard the confidentiality of personal information reviewed by the FCOI Review Committee. Members shall disclose to the Chair any conflicts of interest and sign a Non-Disclosure Agreement with the University prior to commencing their term.
- 6.4. The FCOI Review Committee will meet on a regular basis and a quorum will consist of at least one-third (1/3) of the members of the FCOI Review Committee.
- 6.5. In cases where the FCOI Review Committee determines that it cannot manage the Financial Conflict of Interest, it may require that the Investigator eliminate the conflict or that the Investigator not proceed with the Research. Factors guiding the FCOI Review Committee in these decisions might include such considerations as the involvement of human subjects in the research, the level of risk involved, the nature and significance of the conflict, the potential for a serious adverse impact on the scientific field or on the reputation of the University, and the level of difficulty involved in managing the conflict relative to the benefit of doing the Research.
- 6.6. The following are examples of conditions or restrictions that may be included in a management plan to either manage or eliminate a Financial Conflict of Interest:
 - a) Public disclosure of Financial Conflicts of Interest (e.g. when presenting or publishing the Research);
 - b) For Research involving human subjects, disclosure of Financial Conflicts of Interest directly to participants;
 - c) Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the Research against bias resulting from the Financial Conflict of Interest;
 - d) Modification of the Research plan;
 - e) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the Research;
 - f) Reduction or elimination of the financial interest (e.g. sale of an equity interest); or
 - g) Severance of relationships that create the Financial Conflict of Interest.
- 6.7. Once a management plan is in place it will be reviewed annually, and the Investigator is required to inform the Committee of any changes relevant to the management of the conflict of interest.

- 6.8.** A plan for management or elimination of the Financial Conflict of Interest may also be imposed on an Investigator by another institution as a condition of a sub-award.
- 6.9.** Any plan for the management or elimination of a Financial Conflict of Interest approved by the FCOI Review Committee must be in place before the Research begins. The FCOI Review Committee may decide to permit PHS grant applications to be submitted while it is considering a possible financial conflict of interest with the understanding that the University will not accept the funds unless the conflict can be managed or eliminated.

7. Sub-Recipients

- 7.1.** Where Research requires the University to sub-grant PHS funds to another institution, the University and that institution will enter into an agreement clarifying the roles and obligations of each party regarding disclosure and review of Significant Financial Interests, in addition to management and reporting of any Financial Conflict of Interest.

8. Reports

- 8.1.** Prior to spending any funds under an award or sub-award of PHS Funds the University must report any Financial Conflict of Interest and resulting management plan as determined by the FCOI Review Committee to the PHS Awarding Component and/or grantor of the sub-award.
- 8.2.** Any report required under this section must include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the Financial Conflict of Interest, and to assess the appropriateness of the University's management plan. Elements of the report shall include, but are not necessarily limited to the following:
- a) Project number;
 - b) Principal Investigator;
 - c) Name of the Investigator with the Financial Conflict of Interest;
 - d) Name of the entity with which the Investigator has a Financial Conflict of Interest;
 - e) Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
 - f) Value of the financial interest (within dollar ranges to be set by FCOI Review Committee);
 - g) A description of how the financial interest relates to the PHS- funded Research and the basis for the University's determination that the financial interest conflicts with the Research; and
 - h) A description of the key elements of the University's management plan, including:
 - i. Role and principal duties of the conflicted Investigator in the Research;
 - ii. Conditions of the management plan;
 - iii. How the management plan is designed to safeguard objectivity in the Research;
 - iv. Confirmation of the Investigator's agreement to the management plan;
 - v. How the management plan will be monitored to ensure Investigator compliance; and
 - vi. Other information as needed.
- 8.3.** For any Financial Conflict of Interest arising subsequent to the University's initial report under the award, an additional report will be made and the new Financial Conflict of Interest must be managed, reduced, or eliminated, at least on an interim basis, within sixty (60) days of that identification.
- 8.4.** For any Financial Conflict of Interest previously reported by the University with regard to an ongoing PHS-funded research project, the University will be required, for the duration of the project, to provide to the PHS Awarding Component an annual report that addresses the status of the Financial Conflict of Interest and any changes to the

management plan for the duration of the PHS-funded research project. The Investigator must provide the University with any additional information necessary to complete this reporting requirement.

- 8.5.** The PHS Awarding Component may at any time inquire into the University's procedures and actions regarding conflicting financial interests in PHS-funded research, including a requirement for submission, or review on site, of all records pertinent to compliance with the regulation. The Investigator must provide University with all information necessary to complete this reporting requirement and cooperate with a site review when necessary. The PHS Awarding Component may also decide that further corrective action is needed or that the University has not managed, reduced, or eliminated the conflict of interest in accordance with the DHHS regulations, and may determine that the suspension of funding is necessary until the matter is resolved. The Investigator shall cooperate with University until all concerns of the PHS Awarding Component have been resolved.
- 8.6.** Prior to the expenditure of any PHS funds for Research which is subject to a management plan, the University will publicly disclose details of the Financial Conflict of Interest, either through posting on a University website or as a written response (within a 5 day period) to a request to the Research Services Office. Elements of the disclosure will include the following:
- a) Investigator's name, title and role with respect to the Research.
 - b) Name of the entity with which the Investigator has a Financial Conflict of Interest.
 - c) Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium).
 - d) Value of the financial interest (within dollar ranges to be set by FCOI Review Committee).
- 8.7.** The University will ensure that any information posted on a website is updated as further information becomes available, and no less than annually. Information provided by written response will outline options for obtaining periodic updates on the disclosure. All information to be disclosed by the University in accordance with this section will remain publicly accessible for at least 3 years from the date the information was most recently updated.

9. Violations

- 9.1.** Failure to disclose the existence of a Significant Financial Interest or any other potential conflict of interest by an Investigator may result in disciplinary action by the University and/or suspension of funding or other corrective action imposed by the PHS Awarding Component.
- 9.2.** In the event that an Investigator's failure to comply with this policy has biased the design, conduct or reporting of PHS-funded research, the University will consult with the appropriate PHS Awarding Component or the DHHS regarding appropriate corrective action and the Investigator shall cooperate with University in this process.
- 9.3.** Where the University identifies a Financial Conflict of Interest that was not disclosed by an Investigator, the FCOI Review Committee will, within sixty (60) days of discovery, implement a management plan and within one hundred and twenty (120) days conduct a retrospective review of the Research to determine whether the Financial Conflict of Interest has biased the design, conduct or reporting of the Research. If the retrospective review determines that there is a bias in the Research, the FCOI Review Committee will identify steps to be taken to eliminate or mitigate the impact of the bias on the Research and submit its findings to the PHS Awarding Component.
- 9.4.** Where it has been determined that PHS funded Research involving a clinical trial of a drug or medical device has been conducted by an Investigator with a financial conflict of interest that was not reported or managed by the University, the Investigator may be required to disclose the financial conflict of interest in all future publications related to the Research and to request an addendum to previous publications providing the disclosure of the financial conflict of interest.

10. Records Retention

- 10.1.** The Research Services Office will retain records of all Financial Interest Disclosure Forms and records of all actions taken by the University with respect to such disclosures.
- 10.2.** The University is required to keep Financial Interest Disclosure Forms and all other records related to disclosure, review and management of conflicts of interest for at least three years beyond the termination or completion of the grant to which they relate, or until the resolution of any action by the PHS Awarding Component involving those records, whichever is longer.

11. Training

- 11.1.** Any Investigator currently involved in Research supported by PHS funding, or intending to submit an application for any PHS funding, or at any time joining a Research project with PHS funding, must complete the on-line PHS Awarding Component Training Module
- 11.2.** Completion of each Training Module must be evidenced by the Training Certificate, which must be submitted to the Research Services Office prior to acceptance of an award or sub-award from a PHS Awarding Component.
- 11.3.** Training must also be completed every four years after the initial training, and immediately when any of the following circumstances apply:
 - a) The University revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators.
 - b) The University finds that an Investigator is not in compliance with the University's financial conflict of interest policy or a management plan.

12. Form

[Financial Interest Declaration and Disclosure for Public Health Services Funding Recipients Form](#)

13. Effective Date

Approved: Dr. E. McCauley, Vice-President (Research)

Effective: August 15, 2012