

Implementation of the Public Health Service (PHS) New Financial Conflict of Interest Regulations at York University

A number of U.S. Public Health Service (PHS) agencies, including National Institutes of Health (NIH), have implemented stringent new training and reporting requirements for significant Financial Conflicts of Interest (FCOI) that affect all investigators and co-investigators, their spouses, and their dependent children. Some non-PHS agencies have also adopted the PHS regulations – please see list below.

To remain eligible for funding, all current PHS (including NIH) grantholders and new applicants must follow the steps below:

1. Complete and Submit a Significant Financial Interest Disclosure Form

Investigators holding or applying for PHS funding must submit a Significant Financial Interest (SFI) Disclosure Form listing his or her known financial interests and those of his/her spouse/partner and/or dependent children.

Please download the form here:

1. [PHS York SFI Disclosure Form](#)

Please submit the completed form to David Phipps, Executive Director, Research & Innovation Services (dhipps@yorku.ca) who will forward to Rhonda Lenton, President, York University, the Designated Institutional Official (DIO) for this matter.

If you are submitting an application to a PHS agency (including NIH), you must complete the York SFI Disclosure Form noted above and submit it to David Phipps, Executive Director, Research & Innovation Services (dhipps@yorku.ca) prior to submitting your grant application.

If you hold funding from a PHS agency (including NIH), you must complete the Significant Financial Interest Disclosure Form noted above **annually** and submit it to David Phipps, Executive Director, Research & Innovation Services (dhipps@yorku.ca).

2. Complete the New Training Requirements

All PHS grantholders and all new applicants must complete an [online tutorial](#), retain the Certificate of Completion, and submit a copy of the Certificate to David Phipps, Executive Director, Research & Innovation Services (dhipps@yorku.ca). The online tutorial takes approximately 45 minutes.

Current grantholders must provide certification to ORS that training was completed in order to remain eligible for funding, i.e., before access can be provided to funds issued through NOAs issued on 24 August 2012 or later, the Certificate of Completion must be submitted to ORS.

This training must be completed *prior* to engaging in the research, and every four years thereafter by the anniversary date of first completing the training.

Funders that Require Compliance with PHS Regulations

U.S. PHS Agencies:

1. Agency for Toxic Substances and Disease Registry (ATSDR)
2. Centers for Disease Control and Prevention (CDC)
3. Food and Drug Administration (FDA)
4. Health Resources and Services Administration (HRSA)
5. Indian Health Service (IHS)
6. National Institutes of Health (NIH)
7. Office of Global Affairs (OG)
8. Office of the Assistant Secretary for Health (OASH)
9. Office of the Assistant Secretary for Planning and Evaluation
10. Office of the Assistant Secretary for Preparedness and Response (ASPR)
11. Office of Public Health and Science
12. Substance Abuse and Mental Health Services Administration (SAMHSA)

Non-PHS organizations which have adopted the PHS regulations:

1. Alliance for Lupus Research (ALR)
2. Alpha-1 Foundation
3. American Asthma Foundation
4. American Cancer Society (ACS)
5. American Heart Association (AHA)
6. American Lung Association (ALA)
7. Arthritis Foundation (AF)
8. CurePSP
9. Juvenile Diabetes Research Foundation (JDRF)
10. Lupus Foundation of America (LFA)
11. Patient-Centered Outcomes Research Institute (PCORI)
12. Susan G. Komen for the Cure

****This list is not exhaustive, and the PHS FCOI regulations may apply to other agencies. Please carefully review the guidelines for competitions that you are applying to and if the PHS regulations apply, please submit the York SFI Disclosure Form and complete the training as noted above.****

Background and Context

A number of US Public Health Service agencies, including NIH, have new financial conflict of interest (FCOI) regulations. The purpose of the new guidelines is to promote “objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health Service (PHS) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest”.

The new requirements affect research funded by the following PHS agencies:

- Agency for Healthcare Research and Quality (AHRQ)
- Agency for Toxic Substances and Disease Registry (ATSDR)
- Centers for Disease Control (CDC)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- Indian Health Services (IHS)
- National Institutes of Health (NIH)
- Substance Abuse and Mental Health Services Administration (SAMHSA)

Under the revised US Regulations, one of an investigator's responsibilities is to ensure the investigator avoids activities which place her/him in a conflict of interest between her/his official activities and any other interest or obligation.

Major changes to the US Regulations include:

- A more inclusive definition of "Investigator"
- A revised disclosure process at the application stage
- Lower financial disclosure thresholds
- Disclosure of all activities relating to "Institutional Responsibilities"
- A requirement to disclose sponsored travel
- A new conflict-of-interest training requirement

More Information

The PHS regulations on FCOI apply to researchers who are planning to participate in or are participating in PHS funded research. While all significant financial interests (see below) must be disclosed, the regulations only apply to those that the institution finds to be related to PHS funded research. Please see <http://grants.nih.gov/grants/policy/coi/> for more information as well as the summary below and the full 2011 Revised Financial Conflict of Interest (FCOI) Regulation [Promoting Objectivity in Research \(42 CFR Part 50 Subpart F\)](#).

Significant Financial Interests - Definitions

1. Researchers applying for or holding PHS funding are required to disclose *significant financial interests*. A *significant financial interest* means 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 (the institutional responsibilities of York University faculty members are described in Article 11 Professional Responsibilities of the YUFA Collective Agreement posted on this webpage: <http://fr.info.yorku.ca>):
 - a. 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;
 - b. 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
 - c. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
2. Investigators also must disclose the occurrence of any reimbursed or sponsored travel (*i.e.*, that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, a US Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. The Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the institutional 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.
3. The term *significant financial interest* does not include the following types of financial interests:
 - a. 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;

- 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, or teaching engagements sponsored by a Federal, state, or local government agency, a US Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education;
- d. or income from service on advisory committees or review panels for a Federal, state, or local government agency, a US Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

Small Business Innovation Research (SBIR) Program means the extramural research program for small businesses that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Public Law 97–219, the Small Business Innovation Development Act, as amended. For purposes of this subpart, the term SBIR Program also includes the Small Business Technology Transfer (STTR) Program, which was established by Public Law 102–564.

York University’s Conflict of Interest Policy and Faculty Collective Agreement

York University’s conflict of interest policy (<http://secretariat-policies.info.yorku.ca/policies/conflicts-of-interest-policy-and-guidelines-for-faculty-and-librarians/>) requires disclosure of conflicts of interest and of potential conflicts of interest and states:

A conflict of interest exists when there is a divergence between an academic employee’s personal interests and his or her professional obligations to the University.

The standard that will be applied to determine whether a conflict of interest exists is that of an independent observer who might reasonably question whether the faculty member’s professional actions or decisions are determined by considerations of, or result in, personal gain, financial or otherwise, or benefit to related persons.

The policy applies to the faculty member as well as all of his or her non arm’s length relationships, including but not limited to that of a spouse or spousal equivalent, parent, child or sibling, or person with whom there exists, or has existed, a close personal relationship.

York also has a collective agreement in place with the York University Faculty Association (YUFA) that describes professional responsibilities and defines misconduct in academic research as (see section 11.03 of the YUFA Collective Agreement posted on this webpage: <http://fr.info.yorku.ca>):

- a. any conscious act of fabrication or plagiarism associated with the proposing, conducting or reporting or publication of research, but does not include differences in opinion, honest error or honest differences in interpretation or assessment of data or research results;
- b. material failure to comply with federal or provincial regulations for the protection of researchers, human subjects or the public, or for the welfare of laboratory animals, or

material failure to meet other federal or provincial requirements as agreed to between the parties to the Agreement that relate to the conduct of research;

- c. failure to reveal to the sponsors any material conflict of interest which might be expected, on reasonable grounds, to be unknown to the sponsors and which might influence the sponsor's decisions on whether the employee should be asked to undertake reviews of research grant applications or to test products for sale or distribution to the public;
- d. failure to reveal to the University any material financial interest in a company that contracts with the University to undertake research, particularly research involving the company's products, or to provide research related materials or services. Material financial interest means ownership, substantial stock holding, a directorship, significant honoraria or consulting fees but does not include minor stock holding in publicly traded corporations.

Allegations of misconduct are directed to the President in writing and then investigated as per Article 11 of the YUFA Collective Agreement.

Process for Disclosure of Significant Financial Interests

No later than at the time of application for PHS funded research, significant financial interests as defined above must be disclosed to York University's designated institutional official. Each researcher who is participating in PHS funded research must submit an updated disclosure of significant financial interests annually during the period of the award as well as within thirty days of discovering or acquiring a new significant financial interest.

Process:

- i. Researcher discloses to the designated institutional official by email in confidence through David Phipps, Executive Director, Research & Innovation Services (dhipps@yorku.ca). The designated institutional official is Rhonda Lenton, President, York University, who may refer disclosures to a designate to review as per steps below.
- ii. The designated institutional official or designate determines whether an Investigator's significant financial interest is related to PHS-funded research and, if so related, whether the significant financial interest is a financial conflict of interest. An Investigator's significant financial interest is related to PHS-funded research when the Institution, through its designated official or designate, reasonably determines that the significant financial interest: could be affected by the PHS-funded research; or is in an entity whose financial interest could be affected by the research. A financial conflict of interest exists when the Institution, through its designated official or designate, reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.
- iii. If there is no FCOI: no further action
- iv. If there is a FCOI: a management plan shall be developed and implemented that shall specify the actions that have been and shall be taken to manage the

conflict. These can include but are not limited to: public disclosure of FCOI; for research involving human subjects research, disclosure of the FCOI directly to participants; appointment of an independent monitor; modification of the research plan; change of personnel or responsibilities, or disqualification from participation in all or some of the research; reduction or elimination of the financial interest, or; severance of relationships that create financial conflicts.

- v. Prior to the expenditure of funds, York shall provide to the PHS Awarding Component an FCOI report regarding any Investigator's significant financial interest found by the designated institutional official or designate to be conflicting and ensure that a management plan has been implemented (see below). For FCOIs identified after the initial FCOI report, York must provide an FCOI report within sixty days.
- vi. York is also required to provide, at a minimum, the following information on each FCOI in writing upon request within five business days of a request: the Investigator's name; the Investigator's title and role with respect to the research project; the name of the entity in which the significant financial interest is held; the nature of the significant financial interest; and the approximate dollar value of the significant financial interest (dollar ranges are permissible: \$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 the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value. The note will indicate to the requester that the information is current as of the date of correspondence and is subject to updates on at least an annual basis and within 60 days of identification of a new financial conflict of interest.

Reporting and Documenting Financial Conflicts of Interest to NIH

FCOI required reports to PHS shall include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of the Institution's management plan. Elements of the FCOI report shall include, but are not necessarily limited to the following:

- (i) Project number;
- (ii) PD/PI or Contact PD/PI if a multiple PD/PI model is used;
- (iii) Name of the Investigator with the financial conflict of interest;
- (iv) Name of the entity with which the Investigator has a financial conflict of interest;
- (v) Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- (vi) Value of the financial interest (dollar ranges are permissible: \$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 the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;

- (vii) 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
- (viii) A description of the key elements of the Institution's management plan, including:
 - (A) Role and principal duties of the conflicted Investigator in the research project;
 - (B) Conditions of the management plan;
 - (C) How the management plan is designed to safeguard objectivity in the research project;
 - (D) Confirmation of the Investigator's agreement to the management plan;
 - (E) How the management plan will be monitored to ensure Investigator compliance; and
 - (F) Other information as needed.

York will maintain records relating to all researcher disclosures of financial interests and York's review of, and response to, such disclosures (whether or not a disclosure resulted in a determination of a financial conflict of interest) and all actions under York's policy or retrospective review, if applicable, for at least three years from the date the final expenditures report is submitted to the PHS or, where applicable, from other dates specified in 45 CFR 74.53(b) and 92.42 (b) for different situations.

Training Recipients of NIH Funding

Applications to PHS and sub-grants of PHS funds are processed through the Office of Research Services. Upon notification to ORS that a researcher is preparing an application for PHS funding or will be receiving a sub-grant of PHS funds, ORS will inform the researcher of the FCOI policy and of the researcher's responsibilities to disclose significant financial interests. Prior to engaging in PHS funded work and then at least every four years, the researcher will be required to attend a training session on the PHS regulations. Training will also be required immediately when any of the following occurs:

1. The Institution revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators;
2. An Investigator is new to an Institution; or
3. An Institution finds that an Investigator is not in compliance with the Institution's financial conflict of interest policy or management plan.