

UNIVERSITY OF TORONTO

INVESTIGATOR PROCEDURES

FOR COMPLIANCE WITH THE U.S. PUBLIC HEALTH SERVICE  
FINANCIAL CONFLICT OF INTEREST REGULATIONS

I. INTRODUCTION AND APPLICATION OF THESE PROCEDURES:

These Procedures are made under the University of Toronto's [Policy on Ethical Conduct in Research](#).

The Policy on Ethical Conduct in Research states that the University “expects of its members (which include faculty, students and anyone holding a university post or any office that gives university status, such as that of a fellow or a research associate), the highest standards of ethical conduct in every aspect of research including applications, proposals, the research itself, reports and publication.”

Where research is funded by the U.S. Public Health Service (PHS), which includes the National Institutes of Health (NIH) and other awarding components, 2 U.S. regulations regarding Financial Conflicts of Interest (FCOI) apply: the Regulation [on Promoting Objectivity in Research](#) and the Regulation on [Responsible Prospective Contractors](#), both effective August 24, 2012 (the “Regulations”). The purpose of the Regulations is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under PHS grants, cooperative agreements and contracts will be free from bias resulting from Investigator FCOIs.

The Regulations provide that they apply to all institutions, both U.S. and foreign, applying for or receiving PHS research funding, including funding that is received as a sub-award from another institution, and to each Investigator (defined below) participating, or planning to participate, in such research. All contracts and grants from PHS awarding components, such as NIH, now require the University to agree to be bound by the Regulations as a condition of funding.

These Procedures (the “Investigator Procedures”) set out the obligations of Investigators under the Regulations, as well as applicable FCOI processes, where research is funded by the PHS.

Companion Procedures, the Institutional Procedures for Compliance with the U.S. Public Health Service Financial Conflict of Interest Regulations, (the “[Institutional Procedures](#)”)

set out the obligations of the University with respect to Investigator FCOIs where research is funded by the PHS.

These Procedures and the Institutional Procedures together implement the requirements of the Regulations with regard to PHS-funded research at the University. One of the requirements of the Regulations is that the University must have a written enforced policy on FCOIs for PHS-funded research that complies with the Regulations. These Procedures and the Institutional Procedures together fulfill that requirement.

Anyone who chooses to apply for or accept PHS funding (through the University) or to work on a PHS-funded research project and who meets the definition of Investigator below must comply with these Procedures and, through them, the Regulations. Failure to comply can mean risk of serious consequences, including suspension or termination of funding.

In addition to the PHS and its components, some other U.S. sponsors of research, including some U.S. foundations, have adopted the Regulations. Where the terms of those sponsors' funding contracts or grants require the University to adhere to the Regulations, these Procedures, as necessarily modified for context, will apply.

## II. DEFINITIONS

- **Financial Conflict of Interest (FCOI):** A Significant Financial Interest or Sponsored Travel (both defined below) that could directly and significantly affect the design, conduct or reporting of PHS-funded research.
- **Financial Interest:** 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), whether or not 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.
- **Investigator:** Any person, regardless of title or position, who is responsible for the design, conduct, or reporting of PHS-funded research (whether or not they are paid from PHS funds). This includes, but is not limited to, the principal Investigator (PI) or project director (PD), and may include postdoctoral associates, research staff, students, collaborators, or consultants-
- **Institutional Delegate:** The individual in the University's Office of the Vice President Research and Innovation responsible for the review of Significant Financial Interests, determination of whether an FCOI exists, and approval of management plans under these

Procedures. The University's Institutional Delegate is the Associate Vice-President, Research Oversight and Compliance. (email: [research.integrity@utoronto.ca](mailto:research.integrity@utoronto.ca)).

- **Professional Responsibilities:** An Investigator's professional responsibilities on behalf of the University, which may include, for example, activities such as research, research consultation, teaching, professional practice, administrative activities and institutional committee memberships.
- **Senior/key Personnel:** The principal Investigator or project director, and any other person identified as senior/key personnel by the University in the grant application, progress report, or any other report submitted to the PHS by the University under the Regulations (or, in the case of a research contract for the U.S. government, any other person identified as senior/key personnel in the contract proposal and contract).
- **Significant Financial Interest (SFI):** A Financial Interest that reasonably appears to be related to the Investigator's Professional Responsibilities and:
  1. with regard to a publicly traded entity, the aggregate value of any salary or other payments for services received from the entity during the 12 month period preceding the disclosure plus the value of any equity interest in the entity as of the date of disclosure exceeds \$US5,000;
  2. with regard to a non-publicly traded entity:
    - a) the aggregate value of any salary or other payments for services received from the entity during the 12 month period preceding the disclosure exceeds \$US5,000; or,
    - b) the Financial Interest is an equity interest in the entity of any value; or,
  3. with regard to intellectual property rights and interests (e.g. patents and copyrights), related income of any value (upon receipt of such income).

Sponsored Travel (defined below) is a Significant Financial Interest for the purpose of Parts III to V of these Procedures.

The following are **not** Significant Financial Interests:

- salary, royalties, or other remuneration received from the University by Investigators employed by or appointed at the University;
- income from the authorship of academic or scholarly works;
- income from seminars, lectures, or teaching engagements sponsored by (or from service on advisory committees or review panels for) U.S. federal, state or local governmental agencies, and U.S. institutions of higher education and affiliated research institutes, academic teaching hospitals, and medical centres; or,

- income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles.
- **Sponsored Travel:** Any reimbursed or sponsored travel undertaken by the Investigator that is related to the Investigator's Professional Responsibilities, including travel that is paid on behalf of the Investigator, even if the exact monetary value is not readily available, but not including travel reimbursed or sponsored by U.S. federal, state or local governmental agencies, and U.S. institutions of higher education and affiliated research institutes, academic teaching hospitals, and medical centres. Sponsored Travel is a Significant Financial Interest for the purpose of Parts III to V of these Procedures.

### III. INVESTIGATOR OBLIGATIONS:

#### 1) Training

Investigators must make themselves familiar with these Procedures and signify [Financial Interests Report](#) (FIR) or in another manner as required by the University) that they have read and understood them and agree to comply with them 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 PHS 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 fill in their name for a certificate and save a copy. A copy of the certificate must be forwarded to the appropriate grant officer to ensure that the University can track who has completed training.

Additional training may be required, including when an Investigator joins the University or the University revises these Procedures, or if an Investigator is not in compliance with these Procedures or a management plan.

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

#### 2) Disclosure Of SFIs

Any Investigator planning to participate (or participating) in PHS-funded research or applying for or receiving PHS funds (whether directly or through a subcontract) must disclose to the University's Institutional Delegate his /her SFIs and any SFIs of his/her spouse, common law partner or dependent children.

The principal Investigator is responsible for ensuring that all Investigators involved in her/his PHS-funded research project are aware of these Procedures and make any disclosures required by these Procedures.

a) **What to Disclose**

Investigators must disclose their Significant Financial Interests (including Sponsored Travel). If an Investigator is not sure whether a particular Financial Interest is significant and should be disclosed, he/she should disclose it.

Disclosure of Sponsored Travel must include the purpose of the trip, the identity of the sponsor/organizer, the destination and the duration, and any other relevant information that the University might require (including monetary value).

Annual updates must include any information not previously disclosed and updated information regarding previously disclosed SFIs.

b) **When to Disclose**

Disclosure must be made:

- i. no later than at the time of application for funding from the PHS (or, in the case of a sub-award, from the prime institution);
- ii. at least annually during the period of the PHS award (to update previously disclosed SFIs);
- iii. within 30 days of discovering or acquiring a new SFI; and
- iv. when a new Investigator joins an ongoing project.

c) **How to Disclose**

All Investigators must complete and forward a signed [Financial Interests Report](#) (FIR) to the appropriate grant officer. Should an Investigator disclose an SFI, the grant officer will forward the FIR to the Institutional Delegate for review and determination of whether there is an FCOI.

Investigators should refer to the FIR form for further instructions for its completion and submission.

Where applicable, Investigators must make reasonable efforts to obtain from the entity or individual in which the Investigator has an SFI consent for disclosure of personal or confidential information and forward such consent to the grant officer along with the FIR.

3) **Compliance and Remedies**

Investigators must comply with these Procedures and with any management plan developed to manage an FCOI.

Contravention of these Procedures, including failure to reveal SFIs or failure to abide by any management plan, may constitute research misconduct under the University's [Policy on Ethical Conduct of Research](#) and its companion [Framework to Address Allegations of Research Misconduct](#).

Parts IV and V below set out the actions the University and the PHS will take to ensure compliance and the remedies they can impose in the event of non-compliance.

In the event of non-compliance, access to PHS funds may be suspended and remedial actions and/or sanctions applied in accordance with the University's applicable policies and procedures.

In any case in which the U.S. Department of Health and Human Services (HHS) determines that 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 University as required, the University must require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

In addition to these Procedures and any management plan, Investigators conducting PHS-funded research also remain subject to all of the University's applicable policies and procedures, including without limitation, those with respect to conflict of interest, financial management and research involving human participants. (See the list in Part VI below.)

#### **IV. UNIVERSITY OBLIGATIONS:**

##### **1) Introduction**

The University's obligations (including processes and timelines) under the Regulations are set out fully in the Institutional Procedures.

##### **2) The Institutional Delegate**

The Regulations require that the University designate an Institutional Delegate to solicit and review disclosures of SFIs and determine if an FCOI exists.

##### **3) Review of SFIs**

The Financial Interests Reports that Investigators submit are reviewed by the Institutional Delegate to determine whether any disclosed SFIs relate to the PHS-funded research and, if so, whether an FCOI exists. An Investigator's SFI is related to PHS-funded research when

the SFI could be affected by the PHS-funded research or is in an entity whose financial interest could be affected by the research. An FCOI exists when the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

The Institutional Delegate will consult with the Dean or Principal of the Investigator's academic division (or delegate) and may request further information from the Investigator and consult confidentially with the Investigator and others as necessary.

The decision of the Institutional Delegate is final.

#### **4) Management of FCOIs and Management Plans**

Where an FCOI is found to exist, the University will take such actions as are necessary to manage the FCOI, including developing and implementing a management plan and, where required, conducting a retrospective review (see section 5) below).

The principal Investigator and the Dean or Principal of the Investigator's academic division (or delegate) will develop a management plan, in consultation as appropriate with the Investigator determined to have an FCOI. The management plan must specify the actions that have been and will be taken to manage the FCOI, including a mechanism for monitoring compliance with the management plan until the completion of the subject research project, and will be subject to the approval of the Institutional Delegate. The management plan will specify who is responsible for implementing the management plan and monitoring Investigator compliance until completion of the research. This will ordinarily (but not always) be the Dean or Principal of the Investigator's academic division (or delegate).

Examples of conditions or restrictions that might be imposed to manage an FCOI include, but are not limited to:

- i. public disclosure of FCOIs (e.g., when presenting or publishing the research);
- ii. for research projects involving human subjects research, disclosure of FCOIs directly to participants;
- iii. appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias, resulting from the FCOI;
- iv. modification of the research plan;
- v. change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;

- vi. reduction or elimination of the Financial Interest (e.g., sale of an equity interest); or
- vii. severance of relationships that create financial conflicts.

### **5) Retrospective Review**

If the University identifies an SFI that was not disclosed in a timely manner by an Investigator or, for whatever reason, was not previously reviewed by the University during an ongoing research project, the University will, within 60 days, review the SFI to determine whether it is an FCOI and, if so, implement a management plan.

In addition, where an FCOI was not identified or managed in a timely manner (including failure by the Investigator to disclose an SFI that is determined to be an FCOI or to comply with an FCOI management plan), the University will, within 120 days of determination of non-compliance, complete a retrospective review of the Investigator's activities and the research project to determine whether the research conducted during the period of non-compliance was biased in its design, conduct or reporting.

### **6) Reports to PHS Awarding Components**

The University will report any FCOI determined to exist, together with any applicable management plan, to the PHS awarding component as required by the Regulations. In particular, reports will be made:

- i. before any PHS funds are spent;
- ii. within 60 days of the identification of new FCOIs; and,
- iii. annually for the duration of the research to update the status of the FCOI and any changes to an applicable management plan (normally at the same time as the annual or multi-year progress report is due).

Investigators must cooperate with the University in providing all required reports and related information to the PHS awarding components.

Where a retrospective review is conducted, the University will update the FCOI report to the PHS awarding component as appropriate, and if the University finds bias, it will promptly notify the PHS awarding component and submit a mitigation report to the PHS awarding component, which will include actions taken to eliminate or mitigate the effect of the bias.

The information that must be included in reports is set out in the Regulations and in the Institutional Procedures.



## **7) Public Accessibility of FCOI information**

Information concerning FCOIs where the individual with the SFI is Senior/key Personnel (as defined in Part II above) must be accessible to the public, be updated in accordance with the Regulations, and remain publically available for at least 3 years.

Information concerning any such SFI may be requested in a written request addressed to the Institutional Delegate and the University will provide a written response within 5 business days.

The information will include at minimum:

- i. the Investigator's name, title and role with respect to the research project;
- ii. the name of the entity in which the SFI determined to constitute an FCOI is held; and,
- iii. the nature and approximate dollar value of that SFI.

## **8) Other Obligations of the University**

In addition to the specific obligations set out above, the University will comply with all other institutional obligations mandated by the Regulations (and set out in the Institutional Procedures), including, but not limited to, the following:

- i. posting these Procedures and the Institutional Procedures on the publicly accessible website of the Vice-President, Research and Innovation.
- ii. taking reasonable steps to ensure that a subrecipient (e.g., subcontractor or consortium members) and its Investigators comply with the Regulations by incorporating compliant FCOI terms into the written agreement and reporting FCOIs of subrecipient Investigators to the PHS awarding component
- iii. providing guidelines for the Institutional Delegate for determining whether the SFI is related to the research and, if so, whether it is an FCOI
- iv. making information available, promptly upon request, to PHS and/or HHS relating to any Investigator SFI disclosure and the University's review of, and response to, such disclosure (whether or not an FCOI was found to exist); and
- v. maintaining records relating to all Investigator SFI disclosures and the University's review of, and response to, such disclosures and all actions taken (whether or not an FCOI was found to exist) in accordance with the Regulations (ordinarily for at least 3 years from the date the final expenditures report is submitted or, in the case of a contract, from the date of the final payment).

## V. PHS POWERS

The Regulations set out the following powers of the PHS and its awarding components:

Where the University has notified the PHS awarding component that an Investigator has failed to comply with these Procedures or a management plan and the design, conduct, or reporting of the PHS-funded research appears to have been biased (as per Part IV, paragraph 6) above), the PHS awarding component will consider the situation and, as necessary, take appropriate action, or refer the matter to the University for further action, which may include directions on how to maintain appropriate objectivity in the PHS-funded research project.

The PHS awarding component (and/or HHS) may inquire at any time before, during, or after the award into any Investigator disclosure of SFIs and the University's review (including any retrospective review) of, and response to, such disclosure, regardless of whether the disclosure resulted in the University's determination of an FCOI. The University is required to submit, or permit on site review of, all pertinent records. To the extent permitted by law, the PHS awarding component (and/or HHS) will maintain the confidentiality of all records of SFIs. On the basis of its review of records or other information that may be available, the PHS awarding component may decide that a particular FCOI will bias the objectivity of the PHS-funded research to such an extent that further corrective action is needed or that the University has not managed the FCOI in accordance with the Regulations. The PHS awarding component may determine that imposition of special award conditions, and/or suspension of funding or other enforcement action, is necessary until the matter is resolved.

## VI. ADDITIONAL RESOURCES

### 1) U.S. Regulations

[Promoting Objectivity in Research](#)

[Responsible Prospective Contractors](#)

(Note that the two Regulations are nearly identical, except that 42 C.F.R. Part 50 (regarding the Responsibility of Applicants for Promoting Objectivity in Research) applies to research funded by a grant or cooperative agreement, whereas 45 C.F.R. Part 94 (regarding Responsible Prospective Contractors) applies to research funded by a contract for services or property for the direct benefit or use of the U.S. federal government.)

### 2) NIH Resources

NIH has provided the following educational documents with in-depth information on the conditions under which a disclosure must be made with respect to FCOIs concerning PHS funds:

[Overview on PHS Financial Conflict of Interest](#)

[NIH Video-Cast presentation on the PHS FCOI Regs \(2011: 84 minutes\)](#)

[NIH website extensive FCOI FAQ section](#)

### 3) **Other University Policies and Procedures**

Investigators should be aware of the following University policies and procedures:

#### **Conduct of Research**

- [Policy on Ethical Conduct in Research](#)
- [Policy on Research Involving Human Subjects](#)
- [Framework to Address Allegations of Research Misconduct](#)

#### **Conflict of Interest**

- [Policy on Conflict of Interest – Academic Staff](#)
- [Policy on Conflict of Interest – Librarians](#)
- [Statement on Conflict of Interest and Conflict of Commitment](#)
- [Provost’s Memorandum on Conflict of Interest and Close Personal Relations](#)
- [Policies for Administrative Non-Unionized Staff: Confidential](#)
- [Policies for Administrative Non-Unionized Staff: Professional and Managerial Staff](#)
- [Policies for Research Associates](#)

#### **Financial Administration**

- [Guide to Financial Management](#)
- [Procurement Policy](#)