


**Policies, Procedures, Standard Operating Practices**

No. CR-05

Title: Conflict of Interest in Research	<input checked="" type="checkbox"/> Policy	<input type="checkbox"/> Procedure	<input type="checkbox"/> SOP
Category: General Dept/Prog/Service: Clinical Research Services	Distribution: Organization Wide		
Approved: Vice President, Research Signature: 	Approval Date:	Jun. 7, 2016	
	Reviewed/Revised Date:		
	Next Review Date:	Jun. 7, 2019	

CROSS REFERENCES: (ADMIN-13) "Research Oversight"; ADMIN-06 "Conflict of Interest"; (ADMIN-28) "Business Conduct and Supply Chain Code of Ethics"; (HR-tce-01) "Preservation and Use of Hospital Property"; (HR-esa-09) "Hiring of Relatives"; (PUR-06) "Conflict of Interest"; (PUR-18) "Evaluation Committee"; (PUR-04) "Capital Equipment Procurement"

**1. PURPOSE**

The purpose of this policy is to supplement and support the foundational policies as identified in the cross-reference, while articulating what constitutes a Conflict of Interest (COI) in Research, and to establish procedures for situations that could give rise to a Conflict of Interest in Research.

**2. POLICY STATEMENT**

No Researcher shall take any action or make any decision or enter into a situation that results in a Conflict of Interest for that Researcher or Thunder Bay Regional Research Institute (The Research Institute) Staff member.

Individuals must report and discuss with the person to whom they report all Conflicts of Interest.

Failure to adhere to this policy may result in disciplinary action up to and including termination of employment, engagement, appointment, or contract.

**3. SCOPE**

This policy applies to all Researchers and employees of The Research Institute.

Researchers participating in research funded by the US Public Health Service, which includes National Institutes of Health, must also comply with the Financial Conflict of Interest requirements for US Public Health Service Grant Applicants and Holders or such other requirements of such other funding bodies.

Researchers who are employed by other institutions shall also follow the procedures of that institution.

Part-time Researchers or The Research Institute Staff (0.5 FTE or less) are not required to seek approval for Major Paid Professional Activities that fall outside of their regular hours of work with the Institute(s).

**4. DEFINITIONS**

**Clinical Research Services Department** oversees the registration, development, processing and execution of all human-subject research at The Hospital and The Research Institute.

**Conflict of Interest** will have the definition as per Policy ADMIN-06 "Conflict of Interest"

**Designate** means the person designated by the VPR to receive and review disclosures of Conflict of Interest in accordance with this policy. For Professional Staff, the Designate is

the Chief of Staff. For The Research Institute Researchers, the Designate is the Scientific Director. For The Research Institute Staff, it is their Manager.

**Gifts** (greater than \$50 value) include: travel, accommodation, meals, gift certificates, tickets, devices, products or service, entertainment and the like, including those that might be provided by external sponsors of continuing education programs or conferences in which the participant is playing no role other than that of an attendee, or by external organizations that offer products or services related to the participant's profession in situations in which the participant may be in a position to influence others to use the external organization's products or services.

**Honorarium** is a payment given for professional services that are rendered nominally without charge.

**Immediate Family Members** will have the definition as provided in Policy HR-esa-09 "Hiring of Relatives".

**Institute** means one of The Hospital or The Research Institute, and **Institutes** means both of them.

**Paid Professional Activity** is an activity funded by sources other than The Research Institute or The Hospital that arises from the Researcher's or The Research Institute staff's position and expertise and confers a financial benefit.

*Major Paid Professional Activity*

A Paid Professional Activity is a Major Paid Professional Activity if it involves:

- (a) teaching for remuneration, more than a 0.5 course load per semester, whether at an academic institution or for a professional development program; or
- (b) a commitment to any individual project totaling more than 10 days in a year; or
- (c) any combination of Paid Professional Activities that are likely to exceed 30 days during a year.

*Minor Paid Professional Activity*

A Paid Professional Activity is a Minor Paid Professional Activity if it is not a Major Paid Professional Activity, and includes Honorarium amounts.

**Professional Staff** means those physicians, dentists (including oral and maxillofacial surgeons), midwives and registered nurses in the extended class who are appointed by the Board of Directors of The Hospital and who are granted specific privileges to practice.

**Researcher** means anyone who participates in work, study, research or development activities for research at one or both Institutes using, in any way, facilities or resources owned, operated, rented or administered by one or both Institutes and/or funds of, or funds administered by, one or both Institutes and includes employees, Professional Staff, individuals with scientific appointments in part or in whole at one or both Institutes, research associates, research assistants, clinicians, technologists, trainees/students, and any person with temporary privileges (e.g. visiting researchers, affiliated scientists, etc.) who participate in work, study, research or development activities at one or both Institutes. "The Research Institute or The Hospital Researcher" is a subset of Researchers who have a formal affiliation with one or both Institutes through employment, contract, or an affiliation

agreement.

**Resources** means the facilities, supplies, support staff or students of one or both Institutes.

**Significant Financial Interest** means having or having the expectation to receive: (i) 5% or more of the ownership interest in a single entity; or (ii) anything with a monetary value exceeding \$10,000. Any financial interest in an outside organization (including securities or options regardless of the amount, or payment for consulting work, licensing fees, etc.) shall be deemed to be substantial if the work at one or both Institutes may affect, favourably or adversely, the commercial value of a product or service in which such outside organization has a financial interest.

**"The Hospital"** means Thunder Bay Regional Health Sciences Centre.

**"The Research Institute"** means Thunder Bay Regional Research Institute.

**"VPR"** means Vice-President of Research of TBRI/TBRHSC.

**"Year"** means the calendar year (from January 1<sup>st</sup> to December 31<sup>st</sup> of any calendar year).

## 5. PROCEDURE

### 5.1 DISCLOSURE

See Policy ADMIN-06 "Conflict of Interest" for the foundational policy information. For Research, TBRI or TBRHSC Researchers must disclose all Conflicts of Interest to the VPR or Designate, and Staff to their Manager, in writing in advance or as the Conflict of Interest arises and/or becomes known. This disclosure must include sufficient information to allow the VPR or Designate to accept, reject or require management of a Conflict of Interest. The disclosure must also include notification of any additional reporting obligations related to the Conflict of Interest.

External Researchers must make the disclosure at the time of project registration via the Clinical Research Services Department.

[See Appendix for attached form.]

### 5.2 CONFLICT OF INTEREST BY RECEIVER OF DISCLOSURE

If the person to whom Conflict of Interest disclosures are normally made has a personal interest in the matter to be considered, that person shall refer the matter in writing to the person at the next higher level of authority.

For Conflicts of Interest involving the positions identified below, disclosure will be made, in writing, as follows:

- Manager to the VPR;
- Scientific Director or Chief of Staff to VPR;
- VPR to Chief Executive Officer of The Research Institute/The Hospital acting in the capacity relevant to person from which the COI arose; and
- CEO to Board of Directors of The Research Institute or The Hospital depending on that relevant to position in question.

### 5.3 REVIEW PROCESS

A Conflict of Interest is not permitted without review by the VPR or Designate. The VPR or Designate will review a Conflict of Interest and render a written decision about managing it in a timely manner. The VPR or Designate may attach such terms and conditions to the decision as the VPR or Designate considers appropriate or necessary to manage the Conflict of Interest.

The Designate will provide an annual report to the VPR summarizing all Conflict of Interest disclosures made to the Designate and the plans for managing them. The Designate may request that the VPR review the Conflict of Interest according to the process for disclosures of Significant Financial Interest.

### 5.4 SITUATIONS THAT COULD GIVE RISE TO COI IN RESEARCH

#### 5.4.1 Gifts & Minor Paid Professional Activity

Refer to ADMIN-28 "Business Conduct and Supply Chain Code of Ethics" for the foundation policy information.

No individual shall accept Gifts or engage in Minor Paid Professional Activity with a for-profit organization that is associated with the The Research Institute or The Hospital activities with the exception of small Gifts as token courtesies (i.e. with an estimated value of \$50 or less)

For not-for-profit organizations, and with prior approval of their Manager, individuals may accept Gifts or engage in Minor Paid Professional Activity if they are in exchange for duties or services that are in-line with their role at The Research Institute and The Hospital, or with their profession, or with their status on committees, or as a member, or for other similar reasons.

#### 5.4.2 Major Paid Professional Activities

- (a) For applicable individuals (see Scope section), the request for approval of a Major Paid Professional Activity shall be made in writing to the individual's Manager and shall specify:
  - (i) the category or type of client;
  - (ii) the nature of the work;
  - (iii) an estimate of the time required to perform the work and the compensation for the work;
  - (iv) the extent, if any, of the use of The Research Institute or The Hospital facilities, supplies, support staff or students;
  - (v) any other major paid professional activities that have already been approved in that year or that are continuing from an earlier year; and
  - (vi) the impact the activity will have on the individual's research and/or service responsibilities.

- (b) The VPR, along with the individual's Manager, shall evaluate the request in light of the extent to which the activity will undermine rather than enhance the individual's research and service responsibilities. It is noted that a Researcher is not to be discouraged from, nor unduly restricted in, this sort of activity as it represents an important mechanism for disseminating the knowledge and expertise of the Researcher to the community and for contributing to the Researcher's intellectual and professional development.
- (c) In evaluating the request, the VPR may seek the advice of the CEO and/or COO and/or Scientific Director. With mutual agreement, the individual, their manager, and the VPR will determine the portion of the compensation that will accrue to the individual and to one or both Institutes as appropriate based on real costs or losses incurred.
- (d) The VPR shall consider the request for approval as soon as possible and shall render a decision in writing. The decision will reflect consistency of treatment.
- (e) If it is advisable for a Researcher or The Research Institute Staff to be permitted to undertake a Major Paid Professional Activity that would undermine the individual's meeting of his or her primary duties and responsibilities for one or both Institutes, the VPR may require, in any grant of approval, that the individual take full or partial released time without pay. Moreover, if an individual wishes to continue such activity indefinitely, the individual may be required to relinquish his or her status as a full-time employee/contractor.
- (f) If approval is denied, the individual shall be provided with written reasons for the denial.

#### 5.4.3 Use of Resources

- (a) When an individual wishes to carry out any activities involving the use of Resources for privately undertaken work or work of a Paid Professional Activity entailing more than trivial use of those Resources, the individual shall make a written request to do so to the VPR. The request shall outline the proposed nature of the use of the Resources. [see Admin 13 "Research Oversight" and HR-tce-01 "Preservation and Use of Hospital Property"]
- (b) The VPR shall evaluate the request in light of the extent to which the request can be accommodated without interfering with work carried out by others.
- (c) The VPR shall require payment to one or both Institutes by the Researcher for the use of the Resources to the extent of the actual cost including overhead.

#### 5.4.4. Dealings with Immediate Family Members

- (a) An individual who wishes to carry out any activities involving Immediate Family Members, in any manner, shall request permission to do so in writing from the VPR or Designate. The request shall set out the activity to be carried out and shall indicate why it is desirable for the activity to be carried out, despite the Conflict of Interest. See ADMIN-06 "Conflict of Interest" and HR-esa-09 "Hiring of Relatives".

- (b) The VPR or Designate shall evaluate the request taking into consideration the extent to which special procedures could be instituted in the particular circumstances that would ameliorate the effects of the Conflict of Interest.

#### 5.4.5 Suppliers and Procurement

- (a) Provisions that must be implemented when dealing with Suppliers in procurement activities are included in PUR-05 "Conflict of Interest".
- (b) PUR-18 "Evaluation Committee" and PUR-04 "Capital Equipment Procurement" also outline the requirements when participating in the procurement and evaluation of services, products, or equipment.

#### 5.4.6 Significant Financial Interest

- (a) An individual with a Significant Financial Interest who wishes to carry out research shall request permission to do so in writing to the VPR. The request shall specify the nature of the research and the extent of the interest held in the company or organization for which the research is to be done by the Researcher or the Researcher's Immediate Family Member(s) or persons with whom there exists or has recently existed an intimate relationship.
- (b) Section 5.4.3 will also apply if there is a use of Resources or other costs or impacts incurred.

### 5.5 MANAGEMENT OF CONFLICT OF INTEREST

- (a) Individuals should propose a plan to manage their Conflict of Interest at the time of making a disclosure. The VPR or Designate has the discretion to assess adequacy and impose additional requirements that must be incorporated into the management plan.
- (b) The following conditions or restrictions could be proposed by the Individual to manage a Conflict of Interest (but others may also be included depending on the nature and type of Conflict of Interest):
  - ensuring no direct reporting relationship with research personnel's Immediate Family Members;
  - monitoring of the research by independent reviewers;
  - modification of the research plan, patient recruitment, or sites;
  - independent data collection or data analysis;
  - an independent data monitoring committee;
  - disqualification from participation in all or a portion of the research;
  - divestiture of financial interests;
  - non-acceptance of the gift, goods, or expenses; and
  - severance of relationships that create the Conflict of Interest situation.

### 5.6 CONFIDENTIALITY OF DISCLOSURES

- (a) The disclosure will not be divulged without the written consent, except:

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- internally for the purposes of complying with policies, including this policy;
- for the purposes of complying with applicable laws;
- to cooperate with procedures being undertaken to address allegations of research misconduct;
- where the research team involves other institutions, the institution administering the funds will copy the disclosure to other relevant institutions if a Significant Financial Interest is involved or may be involved; or
- to funding agencies as required; if the research is to be conducted at more than one institution, the institution administering the grant funds will make the required disclosure to the funder.

## 5.7 APPEALS PROCESS

Researchers and The Research Institute Staff may appeal a negative decision to the CEO or, in the case of Researchers covered by the Professional Staff By-laws, through the Medical Advisory Committee process.

## 6. REFERENCES

Granting Agency Policies: Tri-Council Memorandum of Understanding, Schedule 14 (CIHR) & U.S. Regulations 42 C.F.R. 50 Subpart F (National Institutes of Health).

Toronto Academic Health Sciences Network (TAHSN) Statement: "Policy Requirements for a Research Financial Conflicts of Interest (FCOI) Policy", adopted May 2006.

## CONFLICT OF INTEREST DISCLOSURE STATEMENT

NAME:

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POSITION:

DEPARTMENT & ORGANIZATION:

**1. CONFLICT OF INTEREST**

- a) The nature and extent of the Conflict of Interest is:
- b) List the persons involved in the Conflict of Interest:
- c) List the persons who may be affected by the Conflict of Interest:
- d) List all persons who should be made aware of the Conflict of Interest:
- e) Explain any benefits, direct or indirect, that may be derived by you or a related party if the Conflict of Interest is permitted:
- f) Explain how the Conflict of Interest may directly affect – or reasonably appear to influence – your research, teaching, scholarly activities or administrative responsibilities:
- g) Explain the steps you propose to take to mitigate/manage the Conflict of Interest:
- h) Explain why you believe the Conflict of Interest should be permitted:

**In submitting this form, I certify that the above information is true to the best of my knowledge, and that I am in compliance, to the best of my knowledge with applicable laws and regulations and Institute policies related to Conflicts of Interest. I will promptly report in writing to any change in circumstances that may alter the nature or scope of the disclosures made by me in this form or affect the management of such disclosures.**

SIGNATURE: \_\_\_\_\_

DATE: \_\_\_\_\_