

University of Ottawa Heart Institute Policy and Procedure Manual

CONFLICT OF INTEREST

Section: General No: 1-260

Issued By: Administration Approved By: Senior Management

Supersedes: August 20, 2021 Date Approved: September 30, 2022

1. PRINCIPLE

The University of Ottawa Heart Institute (UOHI) and the Ottawa Heart Institute Research Corporation (OHIRC), and the University of Ottawa Heart Institute Foundation, collectively referred to as "the Institute", have an obligation to promote the highest standard of public and stakeholder trust and integrity. The principles of transparency and disclosure are essential to achieving these objectives, and as such, it is expected that Institute Representatives (as defined below) will carry out their duties honestly, responsibly and in accordance with high ethical standards and professional integrity.

It is recognized that relationships exist between Institute and/or Institute Representatives and third parties, and that these relationships are critical to fulfilling the Institute's mission and vision. At the same time, these relationships may give rise to benefits (real or perceived) for Institute Representatives, their close relations and/or the Institute, raising the potential for conflicts of interest to arise. As such, the purpose of this policy is to ensure that the Institute has a comprehensive process in place to identify and address complex relationships with third parties and to adopt a consistent approach to the disclosure and management of these relationships.

This policy sets out the obligations of Designated Staff (as defined below) to complete a Conflict of Interest Disclosure Form upon onboarding and annually thereafter, and of Institute Representatives to provide disclosures on a transactional basis. This policy further details who is responsible for the review and recommendation of management plans for disclosed relationships in a consistent, fair and transparent manner.

This policy does not replace the roles that professional bodies play in regulating ethical conduct or any legislative or regulatory obligations. Institute Representatives are reminded to familiarize themselves with relevant guidance documents or policies issued by their applicable governing professional body(ies), as well as with applicable legislative and regulatory obligations. Certain granting agencies require evidence of mandatory training, as well as disclosure.

The Annual Conflict of Interest Disclosure meets institutional oversight requirements and compliments the Ottawa Health Science Network Research Ethics Boards conflict of interest review, when applicable.

2. APPLICATION

This policy applies to all staff, anyone employed at or hired as a consultant by the Institute, regardless of the source(s) of funding, as well as medical staff members who are not employees, students, trainees, and others working at the Institute ("Institute Representative"). Institute Representatives includes Designated Staff.

Designated Staff include Senior Management and those that participate in decisions for the creation of legal relationships with third parties (procurement, equipment, materials management, technology transfer, human resources). It also includes all Principal Investigators (PIs), Co-investigators, and any other person affiliated with the Institute who holds a basic or clinical research appointment and/or participates in the design, conduct, or review of research at the Institute.

For the purposes of reporting conflict of interests, interests should include those of "close relations" defined as a spouse/domestic partner, dependent children and/or any family member or other person in a close personal relationship who could be perceived to influence an Institute Representative's role, responsibilities, and commitments to the Institute.

3. DEFINING CONFLICTS OF INTEREST

A conflict of interest exists where there is a potential divergence between an Institute Representative's financial, professional, or other personal interest and his/her obligations to the Institute. The standard is whether an independent observer would reasonably question the Institute Representative's behaviour or decision as being motivated by considerations of personal gain, financial or otherwise, from a source other than the Institute. A conflict of interest may be real, apparent, perceived or potential:

- A real conflict of interest arises where an individual has a bias, or a personal, occupational, professional, or
 financial relationship or interest that may affect or compromise, or appear to affect or compromise, his or her work
 with the Institute.
- A perceived or apparent conflict of interest may exist when a reasonable, well informed person has a reasonable belief that an individual has a conflict of interest, even if, in fact, there is neither a real nor a potential conflict.
- A potential conflict of interest incorporates the concept of foreseeability: when an individual can foresee that a
 private or personal interest might someday be sufficient to influence his or her work with the Institute, but has not
 yet (for example, an identified future commitment).

A conflict of interest may arise in various situations:

Financial interest: Institute Representative has a financial interest when he/she stands to benefit from the undertaking or outcome of an activity, which may compromise the Institute Representative's professional judgment in carrying out his/her duties at the Institute (e.g., money, gifts, favours or other special considerations). Undue influence: Institute Representative has a private or personal interest sufficient to impair, influence or appear to influence the objective exercise or his or her duties (e.g., reputation, dual conflicting roles).

4. POLICY

All real, perceived, and potential conflicts of interest must be declared. Additionally, all Institute Representatives must declare if they their position involves working with a close relation; this includes work with close relations at UOHI and collaborations with close relations from other Institutions.

All Institute Representatives shall avoid actions on any manner in which they have a conflict of interest; such actions include, but are not limited to, participation in a decision-making process by discussion or vote. In particular, and without limiting the generality of the foregoing, unless specifically authorized after full disclosure of the conflict and mitigation strategies have been put in place, Institute Representatives shall not:

- knowingly authorize the purchase, with funds administered by the Institute, of equipment, supplies, services or real property from a source in which they or one or more of their close relations have a significant financial interest;
- participate in the management or have significant interest in the ownership of any enterprise which has entered, or proposes to enter, into a contractual or commercial relationship with the Institute;
- knowingly accept gifts, travel or other remuneration from any enterprise which has entered or proposes to enter
 into a contractual, commercial or research relationship with the Institute, unless the remuneration can be
 documented to be on behalf of the Institute or as part of the budget of the program;
- participate in the management, or have interest in the ownership of, any enterprise from or through which one or
 more other representatives of the Institute, or a close relation internal or external to the Institute, receive or may
 receive remuneration for consultative or other services;
- participate in or attempt to influence any proceedings concerning the appointment of a close relation by the Institute or concerning benefits for, in terms or conditions of, employment for such relation;
- participate in the review of a close relation's research work (e.g. internal funding competitions, performance review, award selection, etc.) or participate in administrative decisions that may directly benefit a close relation (e.g. allocation of research/program funding);

- have a direct supervisory role over a close relation in a paid position (see policy 1-30 Nepotism)
- fund paid positions of close relations from their cost centre(s);
- participate in clinical research and/or clinical trials sponsored by organization in which Institute Representative
 owns any equity (shares, warrants and/or options), unless this equity is part of a professionally third party
 managed mutual fund and is disclosed using the disclosure process outlined below;
- use privileged or confidential information, including personal health information, for personal gain;
- have a reciprocal benefit or arrangement with an external organization or individual;
- have outside interests or activities that erode the trust and confidence in the integrity of the Institute by the public and staff; and,
- have outside interests, activities or commitments that impede or could be perceived to impede meeting his/her duty to patients and/or research participants or his/her roles, responsibilities and commitments to the Institute.

Note: If acting as an academic reference for a close relation, this relationship must be disclosed with the reference. Funding agencies, academic journals, and research ethics boards may require Institute Representatives to disclose personal relationships with collaborators according to their organizational policies and procedures.

5. DISCLOSURE PROCESS

Confidentiality: Any information gathered under this Policy shall be held in confidence except for essential purposes (e.g. requirements of the Institute or Research Ethics Board, or where relevant, external organizations, or under compulsion of statute or judicial process). Any disclosure to third parties will be on a need-to-know basis and made subject to confidentiality obligations to the extent possible.

Requirements: Designated Staff must complete Conflict of Interest Training and Disclosure Forms (Appendix A):

The Conflict of Interest Training summarizes the key concepts surrounding conflicts of interest and provides examples for consideration when completing the disclosure.

The Conflict of Interest Disclosure asks about various forms of conflicts. The form completion should be based on activities from the twelve months prior and anticipated activities, services, and other engagements for the year to come.

Training and disclosures must be completed by Designated Staff at the following times:

- Upon hiring as part of the onboarding process before contract execution
- Annually at the end of each calendar year, when notified by Administration and/or Clinical Research & Compliance; no later than December 31.
- On a transactional basis whenever a new potential conflict of interest arises.

Other Institute Representatives are required to complete the form as needed.

Ethical Disclosure: Researchers intending to conduct a clinical research study at the Institute, which is being submitted for Research Ethics Board (REB) review through OHSN-REB or CTO Stream, will be asked to declare study specific conflicts in the application form (as detailed in REB Standard Operating Procedures 105B "Conflicts of Interest – Researcher"). Conflicts declared on Full Board applications will be compared with annual disclosure forms to ensure accuracy and acceptable mitigation strategies, if applicable.

6. REVIEW AND MANAGEMENT PROCESS

Process for Pls and Designated Staff at OHIRC:

OHIRC Human Resources is responsible for the collection of OHIRC new hire Conflict of Interest Disclosures. The Clinical Research & Compliance Office is responsible for the initial review of onboarding disclosures, collection and initial review of annual Conflict of Interest Disclosures for the PIs and Designated Staff at OHIRC, as defined above, and the initial review of COI declarations on Grant Application & Account Request Notices for grant funding. The Conflict of Interest Committee, whose membership includes the CFO, VP Finance & Administration and representatives from Legal Affairs, OHIRC Human Resources, Clinical Research and Compliance Office, Research Services and OHIRC Finance, is responsible for reviewing all declared conflict of interests and will make recommendations on mitigation strategies for declared conflicts, including halting activities if necessary.

In general, when reviewing disclosures where an individual and/or their close relations has received \$3000 or more in a 12 month period from a single source the COI Committee will determine if further disclosure/mitigation strategies are necessary. However, the Committee reserves the right to ask for clarification and may in certain circumstances ask for further disclosure/mitigation strategy be put in place for lesser amounts.

Process for Senior Management and Other Designated Staff:

Finance and Administration is responsible for the annual collection of Conflict of Interest Disclosures for Senior Management and Designated Staff, as defined above. Any declared conflicts will be reviewed by the CFO, VP Finance & Administration. Legal Affairs and/or the CEO will be consulted as needed regarding conflicts and possible mitigation strategies.

7. CONSEQUENCES OF NON-COMPLIANCE

Non-compliance with this policy by Institute Representatives, including a failure to properly disclose or follow a management plan, may be grounds for corrective action, up to and including termination of employment, placement, appointment, or contract with the Institute, or a suspension or revocation of privileges, where applicable.

Furthermore, a serious breach of this policy may be required to be reported to the individual's professional body, if applicable. Any action taken by the Institute that could impact a student's ability to fulfill his or her academic program requirement will be subject to prior consultation with the appropriate personnel at the academic institution, if required.

8. OTHER POLICIES

Institute Representatives must also recognize their responsibilities regarding conflict of interest under the guidelines of the University of Ottawa, The Ottawa Hospital and their respective professional organization.

Related Policies:

1-290 Gifts 1-30 Nepotism

Reference Polices and SOPs:

TOH Policy 1694 – Conflict of Interest OHSN-REB (N2/CAREB adopted) SOP 105B - Conflicts of Interest – Researcher

Note: Appendices are provided as samples of the current versions for reference only; they may be revised independently of this policy with approval of the CFO, VP Finance and Administration, as required.