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”, has 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 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 Disclosure Form annually, and of Institute Representatives to provide disclosures on a transactional basis. This policy further details the procedures that will be followed by, and the role of, Legal Affairs, the Office of the CFO and the Compliance and Risk Evaluation Process (as defined below) in 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.

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, OHIRC Board members*, students, trainees and others working the Institute (“Institute Representative”).

For the purposes of reporting conflict of interests, interests should include those of “close relations” defined as your 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.**

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 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 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.

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.

Annual Disclosures:

Designated Staff must complete annual Conflict of Interest Disclosure forms. Designated Staff include Senior Management and those that participate in decisions for the creation of legal relationships with third parties (equipment, materials management, technology transfer, human resources). It also includes all principal investigators, 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; these individuals must also complete a training module.

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

The Conflict of Interest Disclosure Form (Appendix 1) outlines the various forms of conflicts. The form should be submitted at minimum annually, and be based on activities from the twelve months prior and anticipated activities, services, and other engagements for the year to come. It should be updated whenever a potential conflict of interest arises.

The Conflict of Interest Training Module (Appendix 2) summarizes the key concepts surrounding conflicts of interest. The training should be completed annually by research staff, as mentioned above.

Compliance and Risk Evaluation Process (CoRE):

All researchers intending to conduct a clinical research study at the Institute which is being submitted for full Board REB review through OHSN-REB or CTO Stream must submit to the CoRE process confirmation of any Conflict of Interests related to the study. These conflicts will be compared with their annual disclosure form to ensure accuracy and acceptable mitigation strategies, if applicable.

6. REVIEW AND MANAGEMENT PROCESS

The Board Secretariat will be responsible for collecting OHIRC Board of Directors’ Conflict of Interest Disclosures forms on an annual basis.

All other Conflict of Interest Disclosures will be the responsibility of Finance and Administration and Legal Affairs. A preliminary review of the completed annual disclosure forms will be completed by Finance and Administration and any forms indicating a conflict may exist will be forwarded to the Director of Legal Affairs for review and a determination of whether disclosed interests constitute a conflict of interest. If concerns remain about a potential conflict of interest, they shall be forwarded by Legal Affairs to the Chief Financial Officer for review and a determination on possible mitigation strategies, including but not limited to the implementation of a conflict of interest management plan for the duration of the activity or study. This process will be completed annually.
The Annual Conflict of Interest Disclosure meets institutional oversight requirements and compliments the Ottawa Health Science Network Research Ethics Boards conflict of interest review.

The CoRE Process will be managed by the Clinical Research Compliance and Support Office.

7. CONSEQUENCES OF NON-COMPLIANCE

Non-compliance with this policy by Institute Representatives, including a failure to make proper disclosure 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

Reference Policies:

TOH Policy 1694 – Conflict of Interest