

Responsible Conduct of Research Training

The University of Ottawa Heart Institute (UOHI) promotes and supports the highest standards of research integrity. It expects of its members excellence in all aspects of responsible conduct of research including applications, proposals, the research itself, reports and publications, and financial management.

The Institute abides by the <u>Tri-Agency Framework: Responsible Contract of Research (RCR)</u> and has in place policy <u>6-10 Responsible Conduct of Research</u> which staff must familiarize themselves with.

All staff involved in research are responsible for:

- providing true and accurate information in documents, applications submitted for funding and dissemination;
- applying for funding only if not currently ineligible to apply for and/or hold funds from the Tri-agency or any other funding organization world-wide for reasons of breach of responsible conduct of research policies;
- ensuring the appropriate recognition of contributions from collaborators, students and/or others (e.g. authorship or acknowledgement) (See Policy 6-230);
- obtaining permission from authors for use of materials where applicable (ie confidential, unpublished or patented, etc.) (See **Policy 6-230**);
- revealing any potential, perceived or real conflict of interest (financial or other) that might influence work or related work (See Policy 1-260);
- holding regular collegial discussions among all research personnel to contribute to the scholarly efforts of group members and to provide informal review;
- conducting research in compliance with applicable Tri-Agency requirements and legislation for the conduct of research;
- managing grant funds in compliance with institutional policies and the *Tri-Agency Framework:* Responsible Conduct in Research and the *Tri-Agency Guide on Financial Administration*, inclusive of submission of accurate progress reports according to applicable funding requirements;
- appropriate record retention;
- proactively rectifying a breach of agency policy (e.g. correcting the research record, providing an apology letter to those impacted, repaying funds, retracting publication, etc); and
- if participating in agency review processes, comply with the Tri-agency's *Conflict of Interest and Confidentiality Policy of the Federal Research Funding Organizations* and confirm they are not currently under investigation for an alleged breach of the RCR Framework or other responsible conduct of research policies.

Researchers in a supervisory role are also responsible for:

- supervising and training staff in the designing of research and the processes of acquiring, recording, examining, interpreting, reporting, publishing and storing data; simply editing publications is inadequate supervision;
- training staff on principles of RCR and fostering a positive and constructive research-working environment.

Allegations of Breach of Policy in Research

As per the RCR Framework: "Individuals are expected to report in good faith and confidentially any information pertaining to possible breaches of Agency policies to the Institution where the researcher involved is currently employed, enrolled as a student or has a formal association." The Institute has the same expectation for reporting breaches of Institutional policies.

If you become aware of a breach of policy you must report it, using the <u>RCR Allegation Submission Template</u>, to the Chief Scientific Officer (CSO), or if the allegation involves the CSO to the Chief Executive Officer, with a copy to the Clinical Research and Compliance Office at <u>clinicalresearch@ottawaheart.ca</u>.

Conflict of Interest Training

The University of Ottawa Heart Institute's Conflict of Interest Policy (1-260) should be reviewed upon hire, annually, and anytime there is a question or concern of a conflict.

A conflict of interest may arise when activities or situations place an individual in a real, potential or perceived conflict of interest between their professional duties or responsibilities and personal interests. Conflicts of interest, especially in research, are inevitable but must be disclosed in a transparent manner. Principal Investigators, employees and trainees are responsible for managing any conflicts through disclosure, withdrawal, or other appropriate mechanisms.

In accordance with the policy you are required to review the training information below and provide a disclosure for affiliations (financial or otherwise) with any commercial entity, including but not limited to, the pharmaceutical, biotechnology, medical device, hospital or research equipment/supply industry. It is important that staff understand what and when to disclose a real, potential or perceived conflict of interest.

What Must You Disclose?

All interests, (financial or otherwise) that you or 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, have with any commercial entity, including but not limited to, the pharmaceutical, biotechnology, medical device, hospital or research equipment/supply industry.

Common examples include:

- fees for consulting, lecturing or acting on advisory boards
- royalties collected from inventions, patents and/or copyrights
- equity of any amount (e.g. investments, stocks)
- travel paid by companies on your behalf

You must also disclose if your position involves working or collaborating with a close relation (including those employed by other institutions).

Activities to be Avoided

There are several activities that are also considered conflicts and should not be undertaken unless specifically authorized after full disclosure of the conflict and mitigation strategies have been put in place. Please note that you must familiarize yourself with the policy in its entirety to understand the many situations considered to be in conflict.

Listed below are a just a few examples:

- authorizing or purchasing equipment, supplies, services or real property where you or a close relation have a significant interest
- collaborating with a spouse, family member or close relation on research activities without disclosing the relationship
- having outside interests, activities or commitments that impede or could be perceived to impede meeting your duty to patients and/or research participants or your roles, responsibilities and commitments to the Institute.

When Must You Complete the Conflict of Interest Training and Disclosure?

- As part of the onboarding process for new hires, to be returned to OHIRC Human Resources.
 - Annually thereafter upon notification by the applicable office, but no later than December 31.
 - Research staff must return completed forms to OHIRC Human Resources
 - Senior Management/other staff must return completed forms to the Finance and Administration Office
- You must also update and resubmit the Form should your conflicts, such as financial interests or relationships, change throughout the year.



Confidential

CONFLICT OF INTEREST DISCLOSURE FORM

Name:	Position:	
Department:	Email:	

Please answer the questions below regarding your^{*} affiliation (financial or otherwise) with any commercial entity, including but not limited to, pharmaceutical, biotechnology, medical device, hospital or research equipment/supply industry. Completion should be based on activities from the <u>twelve months</u> <u>prior</u> and <u>anticipated</u> activities, services, and other engagements for the year to come.

*"Your" 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.

1. I am a member of the advisory board (or equivalent) of a commercial entity.

_____ Yes _____ No

- 2. I am a member of a Speaker's Bureau. _____Yes _____No
- I have received payment(s) or honorarium(a) or travel reimbursement from a commercial entity (i.e. for speaking, consultation, participation in meetings, executive position, gifts, etc.).
 Yes _____ No
- 4. I have received a grant(s) from a commercial entity. _____ Yes _____ No
- 5. I hold a patent for a product marketed by a commercial entity. _____ Yes _____ No
- 6. I hold investments (excluding diversified mutual funds and managed funds) in a commercial entity. _____ Yes _____ No
- 7. I am currently working on, or have worked on within the last 12 months, a clinical trial or basic research involving drug(s), device(s), equipment, supply(ies), reagent(s), and/or software in which I have a financial or personal relationship with the sponsor/supplier, or a direct competitor, outside of this research.
 _____Yes _____No
- 8. I hold individual or joint ownership in a commercial entity, which I acquired by purchase or through the provision of services.

_____ Yes _____ No

 I conduct or supervise research not otherwise disclosed in this form that could affect the value of a technology I developed (i.e. compound, drug, device, diagnostic, medical or surgical procedure).
 Yes _____ No

If you answered Yes to any of the above questions, please provide detailed information in the table below You will need a separate line for each commercial entity per question where you answered yes (an example of how to complete the table can be found on page 3).

Q#	Name of Commercial Entity	Total funding received from entity in past 12 months	Description	Ongoing Relationship (Yes/No)

Please answer the following question related to working with close relations.

Does your position involve working or collaborating with a close relation (e.g.: spouse, child, parent or other member of your family or household) internal or external to the Institute?

_____ Yes _____ No

If yes, please provide additional information:

I certify,

- I have reviewed the attached training;
- the information I have provided is true; and
- that all my significant relationships with an entity have been disclosed.

I understand that this disclosure must be updated on a yearly basis or as my situation changes.

Signature

Date

Upon completion of this form return to the applicable office (as distributed to you):

- Pls/Research Staff: Office of Clinical Research & Compliance
- Senior Management/Staff: Finance and Administration Office

For Administrative Use Only							
Form tracked and filed	Committee Reviewed n/a						

Example of completed table:

Q #	Name of Commercial Entity	Total funding received from entity in past 12 months	Description	Ongoing Relationship (Yes/No)
1	ABC Corporation	\$1000	I received compensation for my work on this advisory board	Yes
1	XYZ Company	\$0	I am a member of this advisory; I have not received any funds for this work.	Yes
3	ABC Corporation	\$500	I received reimbursement for travel to a conference to speak on behalf of this company	No
4	LMN Incorporated	\$30,000	I received a grant for the XOXO Study	Yes
6	QRS Company	\$50	Interest and dividends paid out in last 12 months	No