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CONFLICT OF INTEREST POLICY AND GUIDELINES

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CONFLICT OF INTEREST

1.0 Purpose

The Ontario Institute for Cancer Research (OICR) is an innovative translational research organization dedicated to research on the prevention, early detection, diagnosis and treatment of cancer. OICR is responsible for the translation of research findings into products, services and improved clinical practice. In carrying out this mission, OICR is committed to operating with integrity and adheres to the highest standards of business and research ethics.

This policy sets out the expectations of OICR Individuals with respect to the avoidance, disclosure and management of conflicts of interest whether actual, apparent, perceived or potential as they carry out their responsibilities. This policy also provides guidelines and particular examples in Appendix B for identifying situations that may give rise to a Conflict of Interest.

2.0 Scope

This policy applies to individuals employed or engaged by OICR ("OICR Individual") as defined in this policy. The specific requirements for an OICR Individual pursuant to the policy, procedures and guidelines may vary depending upon his/her role and responsibilities, particularly with respect to research.

OICR Individuals conducting research with funds from external agencies/sponsors are expected to adhere to both OICR's Policy and the Conflict of Interest policies and procedures of the agency/sponsor. Most Canadian agencies/sponsors adhere to the Tri-Agency Framework: Responsible Conduct of Research document, which is detailed in OICR's Responsible Conduct of Research and Research Misconduct Policy. Conflict of Interest requirements for the United States Public Health Service (PHS)/National Institutes of Health (NIH) sponsored research have been incorporated into this policy as Appendix A.

OICR recognizes that there may be collaborating external scientists receiving financial support through research grants managed by OICR. These external grant recipients and sub-recipients are not considered OICR Individuals and are expected to comply with all policies, procedures and guidelines of their host institution regarding Conflict of Interest matters, as well as any conditions and obligations relating to Conflict of Interest matters stipulated within their contractual agreements with OICR.

An exception to this would be in cases where OICR is the Lead Institution on a grant provided by the United States PHS/NIH and is providing a subaward to an external institution ("Subrecipient"). In this case, the Subrecipient institution typically complies with their own institutional Financial Conflict of Interest (FCOI) policy, so long as it is compliant with the NIH standard (42 CFR Part 50 Subpart F, or other as directed by PHS/NIH). If they do not have a policy that is compliant with the NIH standard, the Subrecipient may elect to abide by the terms and conditions of OICR's policy to comply with the NIH regulations. The details of FCOI reporting, including whether the Subrecipient will abide by their own policy, or that of OICR, shall be incorporated, in writing, into any resulting subaward agreements between the institutions. Additional policy requirements for NIH applicants and Subrecipients (as applicable) are detailed in Appendix A of this document.

For the purposes of this policy, Conflicts of Interest include Conflicts of Commitment and Significant Financial Interests (SFIs) all as defined below.

3.0 Definitions

Business: Means a corporation, partnership, sole proprietorship, firm, franchise, association, organization, holding company, joint stock company, receivership, business or real estate trust, or other legal entity organized for profit or charitable purposes, but excluding OICR.

Conflict of Commitment: Arises when the Outside Professional Activities of an OICR Individual are so substantial or demanding of the Individual's time and attention so as to adversely affect the discharge of the Individual's responsibilities to OICR, or where the non-OICR activities of an Individual involve the use of OICR resources.

Conflict of Interest (COI): Arises when an OICR Individual finds him/herself in a situation where two or more competing interests conflict and may impair his/her ability to make objective, unbiased or neutral decisions.

Conflict of Interest Committee: Shall have the meaning ascribed to it in section 4.3.4.

Enticement: The giving or receiving by any person of anything of value (usually money, a Gift, loan, reward, favour or other consideration), either directly or indirectly, in order to gain an explicit advantage or influence contrary to the principles of exemplary ethical standards.

Financial Interest: An interest in a business consisting of: i) any equity stock, stock option or similar ownership interest in such business, but excluding any interest in a business arising from an institutional investment (e.g., mutual fund, pension) over which an OICR Individual does not exercise control; ii) receipt of, or the right or expectation to receive, any income from such business (or from an agent or other representative of such business).

Financial Conflict of Interest (FCOI): A Financial Interest that could directly and significantly affect decision making and/or undertaking of an individual's responsibilities to OICR and, when applicable, any PHS/NIH-funded research. This specifically includes potential effects on the design, conduct and reporting of research.

Gifts: Includes not only articles of value, but also includes, and is not limited to, travel, accommodation, extravagant meals, and the like, including those that might be provided by commercial external sponsors of continuing education programs or conferences in which the OICR Individual is playing no role other than that of an attendee, or by external organizations which offer products or services related to the Individual's profession in situations in which the Individual may be in a position to influence others to use the external organization's products or services.

Immediate Family: Includes grandparents, step-grandparent, parents, step-parent, foster parent, brothers, sisters, step-brother, step-sister, spouse, father-in-law, mother-in-law, brother-in-law, sister-in-law, children, step-children, foster children, son-in-law, daughter-in-law, grandchildren, and step-grandchildren of the employee or the employee's spouse or partner.

Non-OICR Activity: Means any activity outside an OICR Individual's scope of work with OICR and includes Outside Professional Activities.

OICR Individual: For the purposes of this policy, OICR Individual refers to an individual employed or engaged by OICR, including PHS/NIH Investigators, temporary and permanent employees, individuals carrying out work who are not paid by OICR, and students. Research collaborators, visiting scientists and

individuals/entities engaged by OICR through professional services agreements are excluded from this definition.

Outside Professional Activity: Means any activity outside an OICR Individual's scope of work with OICR that involves the same specialized skills and knowledge that the member utilizes in his/her work with OICR and includes the operation of a business, consulting or advisory services and speaking engagements.

PHS/NIH Investigator: Means the project director or principal investigator (PD/PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the US PHS/NIH, or proposed for such funding, which may include, for example, collaborators or consultants.

Research staff: Refers to the following individuals—

- **Investigator:** Means the project director or principal investigator (PD/PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by a granting agency, or proposed for such funding, which may include, for example, collaborators or consultants.
- **Researcher:** An individual who performs research bench/laboratory/computer work and documents results/data from research activities (e.g., scientists, research associates, etc.).
- **Research/Program Manager:** An individual responsible for supporting scientific research initiatives through direct management of research staff administratively and through project oversight.

Significant Financial Interest (SFI): An OICR Individual (including his/her Immediate Family) has an SFI and must disclose the item(s) when one or more of the following criteria are met:

- receipt of greater than \$5,000 aggregate remuneration from any publicly traded company in 12 months prior to the date of disclosure; remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
- receipt of greater than \$5,000 aggregate remuneration from any non-publicly traded company or equity holding of any amount;
- receipt of intellectual property rights, royalties from such rights, agreements to share in royalties from such rights; or
- where the OICR Individual has actual knowledge of Immediate Family having met one or more of the above criteria.

For OICR Individuals who apply to, or receive funds from, or Investigators who participate in work funded by the PHS/NIH, SFIs are defined as including all of the above and:

- Travel which is reimbursed or sponsored (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to the institutional responsibilities is allowed, but must be reported as an SFI as prescribed by this policy. The exception would be to reimbursed or sponsored travel that falls below the \$5,000 *de minimis* threshold allowable by the NIH.

4.0 General Policy

All OICR Individuals must take care to avoid actual, apparent, perceived or potential Conflicts of Interest. In carrying out their duties, OICR Individuals are expected to maintain the highest standard of professional integrity and ethical behaviour. OICR Individuals are expected to exercise care in their conduct of the organization's business and to be open and straightforward when the potential for a Conflict of

Interest arises. The primary commitment of intellectual energies, behaviour and time must be to the role(s) and responsibilities of the OICR Individual as expected through his/her employment relationship with OICR.

OICR recognizes that OICR Individuals and/or members of their Immediate Families may seek to engage in activities such as research or commercial endeavours that may include Outside Professional Activities or other Non-OICR Activities and/or involve Financial Interests via relationships with external parties. While these relationships may be beneficial to the participants, OICR and the public, OICR must ensure that these activities are consistent with OICR's interests since these arrangements may also create or have the potential to create Conflicts of Interest. Conflicts of Interest can include Conflicts of Commitment, which can arise when Non-OICR Activities of an OICR Individual interfere with his/her responsibilities to OICR as a result of insufficient time and attention placed on performance of his/her duties, and may also arise naturally from an individual's engagement inside and/or outside OICR. Such arrangements may influence, directly or indirectly, a decision, behaviour or action that might lead an independent observer to reasonably question whether the individual's action was motivated by considerations for personal benefit or that of a member of the individual's Immediate Family, or an individual with whom there exists a close relationship.

In particular, SFIs pose a source of potential Conflict of Interest. OICR's purpose in recognizing, disclosing and managing SFIs is to enhance the likelihood that the management of business related activities and that the design, conduct and reporting of the Institute's research endeavours are free of bias that may be induced by conflicting Financial Interests of an OICR Individual.

OICR Individuals have an obligation to:

- disclose to their supervising manager all matters/activities that may be questionable as per this policy;
- seek approval from their supervising manager and/or OICR's Conflict of Interest Committee prior to engaging in said activities;
- be familiar with the requirements of this policy and associated procedures.

OICR recognizes that each situation depends upon its specific facts. This policy cannot anticipate and provide for every circumstance; OICR has not attempted to develop an exhaustive list of Conflicts of Interest. Rather, OICR expects that OICR Individuals conduct themselves at all times with the highest ethical standards in a manner that will bear the closest scrutiny.

4.1. Potential Sources of Conflicts of Interest

The existence of a Conflict of Interest does not necessarily imply wrongdoing; however, such a conflict must be recognized, disclosed and assessed. OICR recognizes two categories of activities potentially giving rise to conflicts of interest:

- those that are prohibited because they cannot be appropriately managed; and
- those that are permissible if appropriately managed.

Where approval of an activity has been sought and received from an individual's supervising manager and/or Conflict of Interest Committee, the activity shall be deemed not to be a Conflict of Interest subject to compliance with any plan to manage the potential conflict.

Conflicts of Interest may arise with the following:

- use of confidential information;
- receiving/providing Enticements;
- Financial Interest;
- outside business/professional activities or affiliations;
- use of OICR resources/property;
- special treatment;
- personal relationships.

4.1.1. Activities that are Prohibited

The following Conflicts of Interest are prohibited for OICR Individuals:

- using privileged or confidential information for personal gain either while employed or engaged by OICR (or during post-employment in particular circumstances);
- accepting or offering personal rewards (e.g., fees or Gifts) in order to influence business transactions or offer an Enticement while employed or engaged by OICR (e.g., in the case of third parties, such as consultants or contractors, acting on behalf of OICR);
- conducting business on behalf of OICR with an enterprise in which OICR Individuals or a member of one's Immediate Family has a Financial Interest;
- participating in non-OICR projects which conflict with institutional values (e.g., projects funded or supported by the tobacco industry, i.e., manufacturers, the Council for Tobacco Research, or the Smokeless Tobacco Council, or any other organization that acts on behalf of or is sponsored directly or indirectly by the tobacco industry);
- direct reporting relationships between Immediate Family members or individuals with close personal/intimate relationships, including relationships that involve decisions on hiring, firing, promoting, performance evaluation and salary evaluation;
- using or permitting use of OICR assets for significant personal gain or personal business.

The above activities will be considered to be in violation of this policy and OICR Individuals engaged in these prohibited activities will be subject to disciplinary action, unless disclosure and corrective measures are taken upon commencement of the activity/relationship.

Refer to Appendix B for general guidelines regarding a Conflict of Interest.

4.1.2. Activities Requiring Management and Approval

Family Relationships and Intimate Relationships

It is foreseeable that Immediate Family members may be employed or engaged by OICR, and that intimate relationships of a consensual nature between OICR Individuals may arise. Relationships wherein an OICR Individual is in a position of authority over an Immediate Family member or with whom one is engaged in an intimate relationship are not permitted. This is due to the potential influence, authority or power imbalance in these relationships at the workplace.

OICR Individuals in these situations should immediately disclose the relationship to their supervising manager so that appropriate measures are taken. Measures will

include, among other things, reassigning reporting responsibilities to others. OICR does not guarantee that a mutually agreeable reassignment may materialize and reserves the right to decide that the relationships are unmanageable and take other measures, including disciplinary actions, to resolve the particular Conflict of Interest.

Trade or Technical Associations and Professional Organizations

Trade associations, technical associations and professional organizations very often pursue constructive and legitimate aims that OICR supports. Participation in such organizations may, in some cases, create Conflicts of Interest or even legal issues related to competition laws. If any such involvement raises a Conflict of Interest, OICR Individuals should immediately disclose the situation with their supervising manager and seek guidance for their activities.

Boards

OICR Individuals may be asked to serve on the board of directors of other organizations, such as another research institute. While this may be an interesting developmental opportunity for the Individual, these positions can in some cases raise conflicts of interests and legal issues or detract from an OICR Individual's performance at OICR.

When OICR Individuals engage in activities outside OICR, they should always ensure that time commitments required by such outside activities do not infringe upon or adversely affect their ability to perform their responsibilities at OICR. OICR Individuals should always disclose and discuss potential participation on the board of directors of another organization with their manager and obtain written approval before accepting the position. The level of commitment required and the fees involved will be among the factors taken into consideration when deciding whether approval will be granted to the OICR Individual. If approved, the OICR Individual may keep any director's fees and/or expense reimbursements involved; however, all such amounts must be disclosed to OICR annually.

Gifts and Hospitality

Gifts or "token courtesies" of a nominal value or of modest and reasonable hospitality are generally acceptable provided that the OICR Individual uses good judgment and moderation, and that the OICR Individual's objectivity is not influenced.

OICR Individuals shall not encourage or accept Gifts over a nominal amount, nor shall they accept gratuities from any person or organization, which has or seeks to have a business or research relationship with OICR. *All Gifts above the value of \$100.00 require the approval of a manager.*

Hospitality in the ordinary course of business is acceptable provided it is reasonable and modest and neither influences the recipient's objectivity, nor could be construed as doing so. Such hospitality should be limited. For example, attendance at a general business reception for the launch of a new venture would be appropriate whereas tickets to a sporting event would not be appropriate.

If OICR Individuals are in doubt as to whether the hospitality is reasonable and modest, prior approval should be obtained from their manager.

Refer to Appendix B for guidelines regarding Gifts and hospitality.

Use of Institute Assets

Institute assets are to be used for legitimate OICR business purposes. However, OICR Individuals may occasionally use OICR's resources such as a photocopier, telephone or email for personal use provided that there are no measurable costs associated with such use, and other OICR Individuals are not distracted or inconvenienced by the use of those resources. Additionally, in such instances, other OICR policies must be followed. Protection of OICR's assets is the responsibility of every OICR Individual.

Refer to Appendix B for guidelines regarding the use of OICR assets.

Outside Business Activity

OICR Individuals may engage in employment activities outside of OICR and take part in outside activities unless the employment or activities are deemed by OICR to likely give rise to a Conflict of Interest, including a Conflict of Commitment. The work must not conflict, appear to conflict, or potentially conflict with the OICR Individual's position, influence, or ability to perform at OICR. Outside business activities of this nature from which supplemental income and/or equity capital (i.e., Financial Interests) may be derived must be disclosed to and reviewed by OICR to determine if they are permissible.

Where outside employment activities might result in demands incompatible with employment at OICR, or cast doubt on the ability to perform OICR duties in a completely objective and productive manner, OICR Individuals must submit a written disclosure to their manager. If it is determined that a Conflict of Interest exists, OICR Individuals may be required to curtail outside business interests.

Outside Professional Activities of Research Staff

OICR recognizes the benefit to society and researchers that can result from researchers participating in professional activities outside of OICR. In fact, employment contracts of research staff frequently provide for time to engage in professional activities outside OICR. However, prior to engaging in Outside Professional Activities all research staff members must disclose related activities to their manager as per the procedures outlined in this policy in order to develop a conflict management plan and to ensure that the outside professional activities do not constitute a Conflict of Commitment.

Examples of Outside Professional Activities Requiring Approval

The following activities require written approval in accordance with this policy:

- All paid professional activities;
- Non-paid activities that exceed the commitment provided for within an individual's contract;
- External management roles which require a significant time commitment;
- OICR scientists hiring and supervising students or other research staff for non-OICR activities;
- Related to the use of any funds administered by OICR, any act relating to the hiring, supervising, or evaluating of, purchasing from, selling to, engaging in any

commercial transaction with, or conferring or denying any financial or commercial benefit to any member of the scientist's Immediate Family or a person with whom there exists, or has recently existed, an intimate personal relationship;

- Related to the use of any funds administered by OICR, any research undertaken by a scientist for a company or organization in which an SFI (see section 4.2.1) is held by the scientist, any member of the scientist's Immediate Family, or any person with whom there exists, or has recently existed, an intimate personal relationship;
- Hiring OICR staff for external professional activities;
- Any outside activities that involve the use of OICR facilities, supplies or staff; and
- Using OICR administered funds to carry out external research.

Post-Employment Activity

All OICR Individuals, past or present, are bound by this policy. While this policy does not restrict an OICR Individual's ability to pursue post-employment opportunities, OICR Individuals must ensure that their employment after OICR does not create a Conflict of Interest. For the purpose of this policy, employment includes direct employment, membership on a Board of Directors or acting as a consultant. For example, providing advice, guidance or representing services to another organization, based on activities in which the OICR Individual had formerly worked on or made a decision on while at OICR, which would provide an unfair advantage to the other organization in its dealings with OICR, may be in violation of this policy.

OICR Individuals who have been responsible for providing advice and/or making decisions with respect to the funding of recipient projects/programs are specifically precluded from receiving compensation from such recipients for working on the project/program for a period of 12 months. Any exceptional circumstances require consideration and direction of the Conflict of Interest Committee.

All OICR Individuals will continue to be bound by this policy and will ensure all OICR administrative, financial, research, employee and other records are kept confidential after their employment with OICR.

4.2. Disclosure Requirements

Full and complete disclosure is key to protecting the integrity of OICR Individuals, as well as that of OICR. The following are elements that must be disclosed in writing to OICR as requested by OICR and/or as the need arises; this listing is not exhaustive as every situation or questionable activity cannot be foreseen:

- The category or type of client;
- The nature of the work;
- The rationale for undertaking this work or activity;
- The nature and rationale of the use to be made of the facilities, supplies, support or staff;
- The extent of the SFI held in the company or organization for which the work or research is done by the OICR Individual or the Individual's Immediate Family or person with whom there exists or has recently existed an intimate relationship (see section 4.2.1 for further detail);
- Any other professional activities that have already been approved in the present year or that are continuing from an earlier year; and
- The expected impact the activity will have on OICR research, teaching and service responsibilities.

Refer to section 5.0 for disclosure procedures.

4.2.1. Financial Disclosure Requirements

It is important for all OICR Individuals to disclose Financial Interests (including Significant Financial Interests) relating to any activity described in section 4.1 and any other activity that may give rise to a conflict, appear to conflict, or potentially conflict with the OICR Individual's position, influence, or ability to perform at OICR.

In particular, increasing public attention on this matter has translated into requirements, especially from Canadian and US research granting agencies, to obtain reports from institutions regarding any significant financial involvements that could be construed to produce a personal benefit. Refer to Appendix A for additional requirements for OICR Individuals applying for funding from the US PHS/NIH.

In determining the aggregate remuneration, the following will also be included:

- payment on behalf of an OICR Individual (and not reimbursed directly to the OICR Individual so that the exact monetary value may not be readily available) such as for sponsored travel or paid authorships; and
- income from non-profits that are not institutions of higher education.

Remuneration excludes:

- salary or royalties paid to the OICR Individual by OICR;
- income from investment vehicles which are not directly controlled by the OICR Individual, e.g., mutual funds;
- income from academic seminars, lectures, advisory boards, or peer review panels sponsored by government agencies, institutions of higher education, academic teaching hospitals, or a research institute that is affiliated with an institution of higher education.

SFIs may be determined to be Financial Conflicts of Interest (FCOIs) through OICR's internal review process. Also, refer to public disclosure requirements for SFIs in section 4.2.3.

4.2.2. Frequency of Disclosure

- At the time of hire, all OICR Individuals must complete and submit a Conflict of Interest disclosure.
- All OICR Individuals must review and update disclosures at least annually.
- All OICR Individuals are required to review and update additional disclosures prior to engaging in activities or when circumstances change potentially giving rise to a Conflict of Interest, within 30 days, unless pre-approval was received.

The annual disclosure process will be overseen by the VP Corporate Services and Chief Financial Officer (CFO), or delegate.

4.2.3. Making Information Publicly Accessible

OICR makes information available about its policies and procedures relating to the management of Conflicts of Interest, and particularly the management of Financial Conflicts of Interest. The current policies and practices governing these activities are readily available on the OICR intranet and Internet homepage (www.oicr.on.ca/oicr-policies-and-procedures/).

For more information about OICR's management practices regarding Conflict of Interest contact:

Ontario Institute for Cancer Research

Attention: VP Corporate Services and Chief Financial Officer

MaRS Centre

661 University Avenue, Suite 510

Toronto, Ontario

Canada M5G 0A3

416-977-7599; toll-free 1-866-678-6427

4.3. Review Process for Conflicts of Interest

4.3.1. Initial Review for All OICR Individuals

Disclosures by OICR Individuals will be initially reviewed by the OICR Individual's supervising manager. All disclosures will be investigated in a timely and effective manner (normally within five business days) by the supervising manager. (See section 5.0 for details.)

Disclosed Conflicts of Interest may be treated in any one manner as outlined here:

- i. The supervising manager after investigating the relevant circumstances and determining there is no actual or potential Conflict of Interest, may permit the disclosed activity and will document his/her determination.
- ii. Alternatively, the supervising manager, after investigating the relevant circumstances and finding that there may be an actual or potential Conflict of Interest, may determine that it can be managed and will advise and work with the OICR Individual(s) involved to develop and implement a plan to manage or avoid the Conflict of Interest. The supervising manager and the OICR Individual(s) will work to achieve an acceptable solution to the matter. If the manageable Conflict of Interest is resolved to the satisfaction of both parties, the supervising manager will document the resolution and the disclosure shall be deemed not to be a Conflict of Interest.
- iii. Alternatively, the supervising manager, after investigating the relevant circumstances may determine that the disclosed activity is not permissible and inform the OICR Individual of this determination at which point the individual must not proceed or continue with the activity. The supervising manager will document the decision.

Or

- iv. Alternatively, the supervising manager may escalate the assessment of the disclosure to the VP Corporate Services and Chief Financial Officer if he/she is unable to determine whether a proposed activity is permissible.

In any event, the Conflict of Interest Committee must be notified via the VP Corporate Services and CFO any time a COI is identified, regardless of whether the activity was deemed permissible or managed.

4.3.2. Escalating Conflict of Interest Issues for all OICR Individuals

If an OICR Individual's supervising manager determines that:

- i. the disclosed Conflict of Interest of an OICR Individual cannot be resolved to the satisfaction of both parties, or
- ii. there is an actual Conflict of Interest which may or may not be permissible, or
- iii. there may be a significant risk to the reputation of OICR as a result of a potential Conflict of Interest,

the VP Corporate Services and Chief Financial Officer is to be advised by the supervising manager in a timely and effective manner within 10 business days of the request.

4.3.3. Review for Research Staff

Subsequent to initial review of disclosures of Conflicts of Interest from OICR Individuals by their supervising manager(s), disclosures of Conflicts of Interest from research staff designated as "Investigator" on projects supported by research granting agencies (e.g., CIHR, NIH) will be reviewed by the Conflict of Interest Committee.

See section 3.0 for meaning of "Investigator" and "PHS/NIH Investigator" and Appendix A for additional information on the disclosure process for PHS/NIH Investigators.

4.3.4. Terms of Reference for Conflict of Interest Committee

Mandate

The mandate of the Conflict of Interest Committee is to:

- Monitor reports of when a COI is identified, regardless of whether the activity was deemed permissible or managed;
- Monitor Conflicts of Interest of OICR Individuals including compliance with Conflict of Interest management directions;
- Monitor compliance of research staff with SFI disclosure requirements;
- Monitor any relationships of OICR research staff, including industry relationships, that may constitute an actual or perceived Conflict of Interest;
- Determine whether disclosed activities constitute a Conflict of Interest and provide direction with respect to the management of potential conflicts;
- Determine cases to be referred to the President and Scientific Director and the Board of Directors because there may be a significant risk to the reputation of OICR as a result of an actual or potential Conflict of Interest.

Membership

Includes the VP Corporate Services and CFO, Corporate Secretary (Chair), and Deputy Director.

Meetings

The Committee will meet as necessary to address matters referred for the Committee's consideration on a timely basis and at least once annually to receive reports regarding the required annual review and disclosure by all OICR Individuals. Refer to section 5.2.3 for procedures relating to the Conflict of Interest Committee.

4.3.5. Communication of Conflicts of Interest

Initial reviewers (i.e., supervising managers) must provide documentation of all actual Conflicts of Interest, whether permissible or not, to the Human Resources Manager so that the following reporting requirements may be fulfilled:

- Filing of documents within the OICR Individual's Human Resources file;
- Internal institutional reporting;
- External reporting requirements to granting agencies funding affected research;
- Reporting to external institutions when OICR is in receipt of a subaward that includes a requirement to report such instances; and
- Applicable research ethics boards where the Conflict of Interest relates to a research project.

4.4. Training on Conflicts of Interest

All individuals new to OICR are provided with a copy of OICR's COI policy and must review the full policy and provide their attestation prior to beginning work. An overview of the Conflict of Interest policy is provided to all new OICR Individuals as part of an orientation session.

In addition, all research staff members are required to take self-paced training relating to conflicts of interest via an online training program (<https://about.citiprogram.org>), in conjunction with training on responsible conduct of research in accordance with OICR's policy on Responsible Conduct of Research Training. OICR Research Operations tracks and retains records of completed training.

4.5. Reporting Sources of Support for Research

When publishing the results of any research for which funding was supplied, the researcher must name the source(s) of funding in the publication, unless there are contractual terms prohibiting such or explicit approval to do otherwise has been obtained from the person/institution to whom the OICR Individual reports.

4.6. Confidentiality

Except through expressed written consent of the OICR Individual or as required by law or as required by the funding requirements of particular funding agencies, any information gathered about an OICR Individual pursuant to this policy will be held by OICR in strict confidence and will only be available to those individuals who are responsible to OICR for its review, management and administration, and to funding agencies where relevant to an application for research funding to that agency.

Refer to section 4.2.3 for public disclosure requirements.

4.7. Record Retention

Records of all OICR Individuals' disclosures of Conflicts of Interest, review of and response to such disclosures (whether or not a disclosure resulted in a determination of a Conflict of Interest) and all actions taken by OICR within the scope of this policy or retrospective review, if applicable, will be maintained as per OICR's policy on Retention and Disposal of Administrative Records. Specifically, *Form A (no conflict)* will be retained electronically. *Form B (declaration of conflict)* will be retained electronically, and a copy will be filed in the individual's file maintained by Human Resources.

For all such records, as noted above, pertaining to OICR Individuals receiving funds from research granting agencies, records will be maintained for at least seven years from the date of submission of the final expenditures report or, where applicable, from other dates as specified by the agency granting the funds.

4.8. Failure to Comply

Failure to comply with this policy as determined by the Conflict of Interest Committee may result in disciplinary action up to and including employment termination of the OICR Individual, as per OICR's policy on Progressive Discipline. Furthermore, it may be required that breach of this policy be reported to the individual's professional body or legal authorities, if applicable.

OICR will protect itself from losses due to conflicts of commitment wherein OICR Individuals spend excessive and significant time on external commitment, especially in cases where the Individual did not seek prior permission or comply with the directions to manage the Conflict of Commitment. OICR may seek reimbursement for the use of OICR assets and the time of OICR Individuals.

4.9. Whistleblower Protection

OICR extends whistleblower protection to any employee who reports a breach or a potential contravention of applicable legislation, or of OICR's Conflict of Interest Policy. This protection also extends to individuals who refuse to engage in an activity that they believe to be in contravention of applicable legislation or OICR's Conflict of Interest Policy.

Refer to OICR Whistleblower Policy for details.

5.0 Procedures

5.1. Disclosing Conflicts of Interest

All potential Conflicts of Interest must be managed in an open and transparent manner. It is essential that all OICR Individuals maintain an exemplary standard of public trust and integrity.

5.1.1. Disclosure Process for All OICR Individuals

1. Upon commencement of employment and when a change in circumstances requires it, OICR Individuals must review section 4.1 of this policy.
2. OICR Individuals must complete and sign the *Disclosure of Conflict of Interest—Form A* and, if necessary, *Form B* and obtain direction/approval from his/her manager:

- Prior to engaging in any activities that directly or indirectly include any personal business transaction or private arrangement for personal profit that accrues from, or is based upon their appointment/employment with OICR or upon confidential or non-public information gained by reason of their employment with OICR;
 - For any direct or indirect personal business or financial activities that conflict with their official duties and responsibilities, including owning any interest (directly or indirectly) in any organization doing business with OICR;
- as part of the annual attestation request managed by OICR.

5.1.2. Disclosure Process for OICR Individuals with an Actual or Possible Conflict of Interest

1. Upon commencement of employment and when a change in circumstances requires it, OICR Individuals with an actual or possible Conflict of Interest to disclose must complete and sign the *Disclosure of Conflict of Interest—Form A* as per section 5.1.1.
2. OICR Individuals must also review section 4.2.1.
3. OICR Individuals must also complete and sign the *Disclosure of Conflict of Interest—Form B*:
 - Prior to engaging in any outside business and/or professional activity as per section 4.1.2;
 - As part of the annual attestation request managed by OICR.

5.1.3. Disclosure Process for President and Scientific Director

If the President and Scientific Director has an actual, apparent, perceived or potential Conflict of Interest the matter will be disclosed in writing to the Chair of the Governance Committee of the OICR Board of Directors which has responsibility for Conflict of Interest matters. The Chair of the Governance Committee shall respond in writing within 20 business days.

5.2. Managing Conflicts of Interest

5.2.1. Role and Responsibilities of an OICR Individual's Supervising Manager

1. Review all *Disclosure of Conflict of Interest—Form A and Form B*, which are submitted by OICR Individuals upon commencement of employment.
2. Review all additional *Disclosure of Conflict of Interest—Form A and Form B*, which may be submitted by OICR Individuals when changes occur in a timely manner (normally within five business days).
3. Where an OICR Individual seeks approval for the disclosed activity/interest the manager may, in his/her discretion:
 - i. grant written approval documenting the rationale, without requiring further action, taking into consideration, and without limiting his/her discretion, the following:
 - the provisions of this policy;
 - the impact on the Individual's obligations to OICR;
 - the degree to which the proposed action will be detrimental to OICR's interests, or in the research context, the degree to which it may

- compromise a Research Staff's professional judgement in conducting or reporting research;
 - the degree to which the activity contributes to or benefits OICR in such a way that warrants the interference;
- OR
- ii. determine the activity to be permissible only if appropriately managed by a Conflict of Interest management plan developed, implemented and monitored by the manager;
- OR
- iii. determine that the activity is not permissible;
- OR
- iv. refer assessment of the disclosure to the Conflict of Interest Committee for determination if he/she is unable to determine whether a proposed activity is permissible.
4. All decisions, corrective actions and conflict management plans made by the Individual's manager and/or the Conflict of Interest Committee regarding an Individual's disclosure must be communicated to the Individual in writing and a copy of the documentation must be included in the Individual's file maintained by Human Resources, via the attention of the VP Corporate Services and CFO.
 5. Monitor compliance with the management plan developed in response to the requestor's disclosure.
 6. Monitor training requirements.

5.2.2. Role and Responsibilities of the VP Corporate Services and Chief Financial Officer

1. The VP Corporate Services and CFO, or delegate, is accountable for OICR's Conflict of Interest disclosure and reporting process.
2. The VP Corporate Services and CFO shall notify the Chair of the Conflict of Interest Committee of all requests for approval that have been forwarded for deliberation.

5.2.3. Role and Responsibilities of the Conflict of Interest Committee

1. Review reports when a COI is identified, regardless of whether the activity was deemed permissible or managed;
2. Review all disclosed Conflicts of Interest of OICR Individuals as reported by:
 - i. Human Resources annually and when changes occur; or
 - ii. an employee's manager; or
 - iii. the OICR Individual,and render a decision in writing within 10 business days of provision. Particular attention will be paid to disclosures that originate from OICR Research Staff.
3. The Committee will discuss all Conflict of Interest activities/relationships that have been deemed non-permissible by the OICR Individual's supervising manager, or for which the supervising manager has requested assistance with a determination and/or development of a management plan. All determinations will be recorded for reporting purposes and for communication to the requestor.
4. The Committee may ask any OICR Individual and in particular any affected researcher to meet with the Committee either in person or via teleconference.

5. The Chair may require that the identity of the client and any pertinent financial details of the specific activity be revealed by the OICR Individual on a strictly confidential basis.
6. The request shall be evaluated in a fair manner to both protect the interests of OICR and to encourage OICR Individuals and Research Staff to participate in other professional activities as such participation represents an important mechanism for disseminating the knowledge and expertise of Researchers to society and for contributing to a Researcher's intellectual and professional development.
7. In the event that the Conflict of Interest Committee needs to seek advice from outside advisors when deliberating the request, this will comply strictly with the principle of confidentiality.
8. If the request is denied, the rationale will be explicit in a letter of denial provided to the requestor and filed in the requestor's Human Resources file.
9. If the request is denied by the Conflict of Interest Committee, the requestor may appeal the process by writing a letter to the Corporate Secretary to bring this to the attention of the President and Scientific Director within 10 business days of the decision. The President and Scientific Director may make a final determination or refer the matter to the Governance Committee of OICR's Board of Directors. The requestor will be advised of the outcome of the appeal within 20 business days.

5.2.4. Role and Responsibilities of the Chair of the Governance Committee of the OICR Board of Directors

1. Review any disclosures involving the President and Scientific Director or both the Deputy Director and the President and Scientific Director and make a determination and/or management plan within 20 business days of receipt.
2. Monitor compliance with the conflict management plan developed to address the Conflict of Interest disclosed.
3. Receive a report annually with respect to the administration of and compliance with this policy.

5.3. Timing of Disclosure

5.3.1. Minimum Disclosure for all OICR Individuals

1. The Human Resources team will request review of this policy and disclosure of any conflicts of interest using Forms A and B (see Appendix B) from each new individual employed or engaged by OICR on or prior to his/her start date.
2. The Finance team will request review of this policy and disclosure of any changes to conflicts of interest from all OICR Individuals once annually.
3. An OICR Individual is required to disclose all Conflicts of Interests whether actual, apparent, perceived or potential to his/her supervising manager prior to engaging in the questionable activity in order that a conflict management plan may be developed.

6.0 Related Documents

- Ethics and Integrity of Research;
- Responsible Conduct of Research and Research Misconduct Policy;
- Whistleblower Policy.

7.0 References

- Financial Conflict of Interest Regulation, 42 CFR Part 50;
- Financial Conflict of Interest Regulation, 45 CFR Part 94;
- The University of British Columbia Board of Governors Policy No. 97: Conflict of Interest and Conflict of Commitment (last revised March 2005);
- Conflict of Interest/Conflict of Commitment—An Issues Paper; Tri-Agency.

8.0 Revision History

Policy Number	Revision Date (YYYY-MM-DD)	Level of Change	Revision Comments
HR-010-002	Not applicable	No change	<ul style="list-style-type: none"> • New document
HR-010-002	2008-07-28	Undocumented	<ul style="list-style-type: none"> • None
AD-GEN.102.002	2009-12-11	Minor change	<ul style="list-style-type: none"> • Copy edited and formatted; • Policy number added; • Revision history added.
AD-GEN.102.003	2010-04-22	Major change	<ul style="list-style-type: none"> • Modified section (x) Post-Employment Activity as per OICR Board-approved language
AD-GEN.102.003	2011-04-15	Minor change	<ul style="list-style-type: none"> • Added reference to OICR's Tobacco Policy; • Changed "OICR employee" to "OICR Individual"; • Corrected COI example provided on p.4; • Copy edit and OICR logo update
AD-GEN.102.004	2012-07-31	Major change	<ul style="list-style-type: none"> • Re-structured majority of document to reflect new requirements from the National Institutes of Health; updates as per re-organization of OICR executive roles and committees; revisions to both disclosure forms; • Added clearer distinction between activities that are prohibited and those that may be managed with an effective Conflict of Interest management plan; • Introduced greater disclosure requirements regarding Financial Interests; • Greater procedural details added; • Updated Sponsor and Issuing Authority from

			<p>Vice-President, Operations to Chief Financial Officer; updated listing of content reviewers;</p> <ul style="list-style-type: none"> • Changed review period from two years to three years.
AD-GEN.102.004	2013 12 09	Minor Change	<ul style="list-style-type: none"> • Various tasks/responsibilities shift from Chief Operating Officer and Chief Scientific Officer to Chief Financial Officer; • Additional roles/responsibilities of the Conflict of Interest Committee, now chaired by the Corporate Secretary; • Upon the commencement of employment, each new hire must review and complete the attestation; • Changes in an individual's Conflict of Interest situation that occur during the periods between annual attestations must be reported at the time they occur; and • Record retention changed from a minimum of three years to seven years, to comply with generally accepted record retention guidelines in Canada.
AD-GEN.102.004	2014 05 22	Minor Change	<ul style="list-style-type: none"> • Added that an indication of the source(s) of funding for research projects be stated.
AD-GEN.102.004	2017 04 03	Major Change	<ul style="list-style-type: none"> • Re-structured several sections of document to better reflect the current National Institutes of Health requirements; • Updated responsibilities to reflect CFO as the FCOI for NIH reporting; • Added responsibilities for Sponsored Awards Officer regarding PHS/NIH Investigators; • Greater procedural details added.

AD-GEN.102.005	2017 05 29	Major Change	<ul style="list-style-type: none"> • Added a new Appendix (Appendix A) to significantly update and more clearly outline policy requirements for PHS/NIH Funded Researchers; • Added paragraph to "Scope" regarding research funded by external agencies/sponsors; • Title change from "CFO" to "VP Corporate Services and CFO"; • Amended the definition of "Significant Financial Interest" in terms of Immediate Family; • Removed redundant Terms of Reference from the Mandate of the COI Committee; • Specified that Form Bs are retained electronically, and a copy will be filed in an individual's file with HR; • Removed certain roles and responsibilities of the COI Committee, including those about convening the Committee and rendering a decision within a certain timeframe; • Wording changes.
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Policy Title	Conflict of Interest Policy and Guidelines		
Associated Form(s):	Disclosure of Conflict of Interest Form A; Disclosure of Conflict of Interest Form B		
Policy Number:	AD-GEN.102.005		
Section:	Administrative – General Administration and Risk Management	Pages:	39
Sponsor:	VP Corporate Services and Chief Financial Officer	Review Period:	3 years
Content Reviewer(s):	Corporate Secretary; Deputy Director; VP Corporate Services and Chief Financial Officer; Director, Grants and Awards; Sponsored Awards Officer	Date of Origin:	October 4, 2007
Issued By:	VP Corporate Services and Chief Financial Officer	Last Modified:	May 29, 2017
Approved By:	Board of Directors	Review Dates:	June 22, 2017; December 9, 2013;

			April 15, 2011; April 22, 2010; December 11, 2009; July 28, 2008.
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Appendix A: Additional Policy Requirement for PHS/NIH Funded Researchers¹

¹ In accordance with the United States Public Health Service (PHS) and the National Institutes of Health (NIH) rules and regulations.

The policies/processes outlined in the above sections are applicable to all OICR Individuals, including those who apply for funding from the US PHS including the NIH. In addition to the policies above, PHS/NIH Investigators must also adhere to the additional conditions below to ensure compliance with OICR and PHS/NIH specific requirements. Complete details of the NIH policies can be found in the US Federal Register 42 CFR Part 50.

For OICR Individuals who apply to, or receive funds from, or Investigators who participate in work funded by the PHS/NIH, SFIs are defined as:

(1) A Financial Interest consisting of one or more of the following interests of the Investigator (and those of their Immediate Family) that reasonably appears to be related to the Investigator's institutional responsibilities:

(i) With regard to any publicly traded entity, a Significant Financial Interest exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

(ii) With regard to any non-publicly traded entity, a Significant Financial Interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's Immediate Family) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

(iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(2) Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

(3) The term Significant Financial Interest does not include the following types of Financial Interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical centre, or a research institute that is affiliated with an

Institution of higher education; or income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical centre, or a research institute that is affiliated with an Institution of higher education.

A.1. Potential Sources of Conflicts of Interest, and Activities Requiring Management and Approval for PHS/NIH Applicants

In addition to those activities outlined in section 4.1.2, PHS/NIH Investigators must also obtain approval for the following activities:

Reimbursed or Sponsored Travel

Travel which is reimbursed or sponsored (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to the institutional responsibilities is allowed, but must be reported as an SFI as prescribed by this policy. The exception would be to reimbursed or sponsored travel that falls below the \$5,000 *de Minimis* threshold allowable by the NIH.

Refer to Appendix A for guidelines regarding the reporting of reimbursed or sponsored travel for PHS/NIH Investigators.

A.2. Disclosure Process for PHS/NIH Investigators

PHS/NIH Investigators are to follow the processes for declaration outlined in section 5.1 above. In addition, PHS/NIH Investigators must review and comply with sections 4.2.1 and 4.2.2, and must adhere to the following additional terms:

- PHS/NIH Investigators must use the *Disclosure of Conflict of Interest—Form B* to:
 - disclose in writing within 30 business days of acquiring a new SFI; and
 - disclose in writing, no later than at the time of application for PHS/NIH funding

Additionally, when an Investigator who is new to participating in the research joins a PHS/NIH-funded project, that Investigator must also ensure that they have followed all processes for PHS/NIH Investigators outlined in this policy before undertaking any PHS/NIH-funded research activities.

PHS/NIH Investigators will need to send confirmation to the Sponsored Awards Officer that their OICR Disclosure of Conflict of Interest form is up-to-date and accurate before any application materials/documents will be submitted to the sponsor or lead institution. If new disclosures are necessary, the PHS/NIH Investigator must follow the standard OICR disclosure procedures, detailed in section 5.1, to update their disclosure. Documents/materials will only be submitted to the sponsor or lead institution once the new forms have been completed and submitted.

A.3. Initial Review for PHS/NIH Investigators

In addition to the processes outlined in section 4.3, disclosures by PHS/NIH Investigators will be initially reviewed by the OICR Individual's supervising manager. All disclosures will be investigated in a timely and effective manner (normally within

five business days) by the supervising manager (for details, see section 5.0). The supervising manager will need to determine whether the reported SFI/COI is related to the PHS/NIH-funded research (see below). Whenever an SFI/COI is identified that is related to the PHS/NIH-funded research, the supervising manager must inform the VP Corporate Services and CFO who will follow up with the sponsor, as necessary (section A.6. Institutional Reporting to PHS/NIH Awarding Components).

Prior to having a cost centre set up for new PHS/NIH funds, PHS/NIH Investigators will need to re-confirm that their OICR *Declaration of Conflict of Interest Forms* are up-to-date and that there are no potential conflicts related to the PHS/NIH-funded project. New conflicts will need to be disclosed following the standard procedures set out in this policy, and will be managed accordingly.

Within 60 days of a PHS/NIH-related SFI/COI being disclosed, the VP Corporate Services and CFO, or delegate, and supervising manager, with the oversight of the COI Committee, will work together to develop and implement a management plan for the PHS/NIH Investigator. The VP Corporate Services and CFO, or delegate, will report the SFI/COI to the PHS/NIH in line with the procedures outlined in sections A.5, A.6, and A.7. Making Information Publicly Accessible

An Investigator's SFI is related to the research when the Institution, through its Designated Official(s) (supervising manager, VP Corporate Services and CFO or delegate, and/or Conflict of Interest Committee), reasonably determines that the SFI:

- could be affected by the PHS/NIH-funded Research; or
- is in an entity whose Financial Interests could be affected by the research

A FCOI exists when the Institution, through its Designated Official(s), reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS/NIH-funded research.

A.4. Retrospective Continuing Review for Recipients of PHS/NIH-Funded Grants

COIs will be monitored on a continuous basis for all PHS/NIH-funded research projects. In addition to monitoring, reviews will be initiated as deemed necessary by the Sponsored Awards Officer who will notify the VP Corporate Services and CFO, under the following circumstances:

- when an Investigator who is new to participating in the research joins a PHS/NIH-funded project; and
- when a PHS/NIH Investigator discloses a new SFI.

In both cases, the supervising manager and/or VP Corporate Services and CFO, or delegate, will, following the process outlined in section 5.0 to review disclosures, make a determination of FCOI, and implement and monitor a management plan as per section A.5.

Whenever an FCOI is not identified or managed in a timely manner, including failure by the grant recipient to disclose an SFI, failure by OICR to review or manage an FCOI, or failure to comply with the management plan, the VP Corporate Services and CFO, or delegate, will, within 120 days of the determination of noncompliance, complete a retrospective review of the recipient's activities and the project to determine bias in the design, conduct or reporting of such research. The VP Corporate Services and CFO, or delegate, will notify the sponsor promptly and submit a mitigation report when bias is found (section A.6).

When a retrospective review is conducted, the VP Corporate Services and CFO, or delegate, will ensure that the key elements of the retrospective review include:

- Project number;
- Project title;
- Name of grant recipient (e.g., PI);
- Name of the researcher with the FCOI;
- Name of the entity with which the grant recipient has an FCOI;
- Reason(s) for the retrospective review;
- Detailed methodology used for the retrospective review; findings and conclusions of the review.

If the results of the retrospective review warrant the VP Corporate Services and CFO must update the previously submitted FCOI report sent to sponsor (section A.6) and will instruct the award recipient to:

- disclose the FCOI in each public presentation of the results of the research; and
- make addendums to previously published presentations.

A.5. Managing Conflicts of Interest: Roles and Responsibilities

A.5.1. PHS/NIH Applicant's Supervising Manager

In addition to the roles and responsibilities outlined in section 5.2.1 above, supervising managers of OICR Individuals who apply for PHS/NIH funds must:

- review all *Disclosure of Conflict of Interest – Form A* and *Form B* which are submitted by OICR Individuals in response to a PHS/NIH application; and
- determine if any of the Investigator's disclosed COIs are related to the PHS/NIH application and if they are, report them to the VP Corporate Services and CFO for management plan development and follow-up.

A.5.2. The VP Corporate Services and CFO

Following identification of an FCOI for a PHS/NIH Investigator, the VP Corporate Services and CFO will notify the Deputy Director, or delegate, who will develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage the FCOI. The management plan shall be in place, modified as necessary, and monitored by the Deputy Director, or delegate, until the completion of the PHS/NIH-funded research project. Examples of conditions or restrictions that might be imposed include:

1. Public disclosure of FCOIs (e.g., when presenting or publishing the research).
2. For research projects involving human subjects research, disclosure of FCOIs directly to research participants.
3. 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.
4. Modification of the research plan.
5. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research.
6. Reduction or elimination of the Financial Interest (e.g., sale of an equity interest). Or
7. Severance of relationship that create financial conflicts.

A.6. Institutional Reporting to PHS/NIH Awarding Components

The VP Corporate Services and CFO will be delegated the role of "FCOI" on the NIH's electronic reporting system the eRA Commons, to facilitate the disclosure of FCOIs to the agency and shall provide initial and ongoing reports (at least annually) prior to the expenditure of agency funds relating to a particular research project for which an FCOI has been determined.

The VP Corporate Services and CFO will also provide initial and ongoing reports of identified FCOIs of sub-recipients of PHS/NIH-funded research grants, as required by the requisite executed funding agreement(s) (section 2.0).

For reporting to the NIH, the Deputy Director, or delegate, will advise the VP Corporate Services and CFO of any new FCOIs and the VP Corporate Services and CFO will report these, including the participation of new Investigators to the NIH-funded project who disclose an FCOI, within 60 business days of identification during the period of the award.

The VP Corporate Services and CFO will notify the NIH sponsor promptly when a grant recipient fails to comply with this policy or when a Conflict of Interest management plan appears to have biased the design, conduct, or reporting of the PHS/NIH-funded research, or following a retrospective review to update a previously submitted report, if appropriate. If bias is found, the VP Corporate Services and CFO shall promptly notify the PHS Awarding Component and submit a mitigation report. The mitigation report will include the following information:

- The key elements documented in the retrospective review;
- A description of the impact of the bias on the research;
- The Institution's plan of action, or actions taken to eliminate/mitigate the effect of the bias.

A.7. Making Information Publicly Accessible

OICR makes certain information available concerning SFIs of Research Staff supported by PHS/NIH funds in compliance with PHS/NIH regulations. When an SFI held by a PHS/NIH Investigator meets the following criteria, OICR shall make information about the SFI available, in writing, to any Requestor:

1. The SFI was disclosed and is still held by the PHS/NIH Investigator. And
2. OICR has determined that the SFI is related to the PHS/NIH-funded research. And
3. OICR has determined that the SFI is an FCOI.

If all three (3) criteria above are met, OICR will provide a written response to any Requestor within five (5) calendar days of a request. The information to be made publicly available includes the following:

- Investigator's name;
- Investigator's title and role with respect to the research project;
- Name of the entity in which the SFI is held;
- Nature of the SFI; and
- Approximate dollar value of the SFI (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one where the value cannot be readily

determined through references to public prices or other reasonable measures of fair market value.

Written responses will be subject to updates. The information will be updated as necessary at least annually, or within 60 days of a newly identified FCOI and provided to a Requestor if so requested.

The information shall remain available for three (3) years from the date of the most recent update of the information.

A.8. Frequency of Training on Conflicts of Interest PHS/NIH Investigators

Prior to any PHS/NIH Investigator engaging in research related to a PHS/NIH-funded project, he/she must complete training on conflicts of interest (section 4.4). This training must be renewed at least once every four years. OICR will ensure that affected individuals will receive training on conflicts of interest when the OICR or PHS/NIH Conflict of Interest policy is revised in a manner that affects the individual or when OICR finds that the individual is not in compliance with this policy or a Conflict of Interest management plan. The OICR Research Operations team will provide a notice to affected individuals that they are due to complete or renew their training.

Appendix B: Additional Guidelines to Assist in Determining a Conflict of Interest

I) General Guidelines regarding a Conflict of Interest

The following questions may assist in identifying whether a situation/relationship is potentially a Conflict of Interest:

- Do I have personal or private interests that may conflict or be perceived to conflict with my public duty?
- Could there be benefits for me now or in the future that could cast doubt on my objectivity?
- Do I or members of my family or individuals with whom I have a close personal relationship stand to gain anything by virtue of my relationship with the third party doing business with OICR or vice versa?
- How will others view my involvement in the decision or action?
- Do I feel any pressure/obligation due to the relationship I have with the third party doing business with OICR?
- Would I be embarrassed if anyone inside OICR knew about the situation?
- How might it look to someone outside OICR, such as a partner or supplier? Would they question whether they have been treated fairly?
- Could my involvement appear unfair or unreasonable in any circumstance?

If the answer to any of the above questions is “yes” or “perhaps” or could be perceived by third parties to be “yes” or “perhaps” you are involved in a Conflict of Interest. If you are not certain, you should seek guidance from your manager.

II) Gifts and Hospitality

i) Questions to Help Determine Conflicts of Interest related to Gifts or Hospitality

You may consider the following questions in relation to Gifts or hospitality:

- Would the Gift or hospitality likely appear to influence my objectivity or the objectivity of the person receiving the Gift or providing the hospitality?
- Would my impartiality or the impartiality of the person receiving the Gift or hospitality be compromised in any way or appear to others to be compromised?
- Is the hospitality for a private purpose rather than a business purpose? For example is business going to be discussed as part of the event or only in a very limited way?
- Would the Gift or hospitality be considered unique or extraordinary? Is the value of the Gift above \$100.00?
- Would it be a problem or embarrass the Gift giver if the Gift or hospitality were disclosed to other employees or third parties?

If the answer to any of the above questions is “yes” or “perhaps” or could be perceived by third parties to be “yes” or “perhaps”, accepting or offering such Gifts or hospitality is most likely in violation of this policy. If there is any uncertainty, you should seek guidance from your manager.

ii) Guidelines relating to Gifts and Hospitality

The giving or receiving of Gifts and hospitality that are of the nature of token courtesies are part of everyday business life. However, inappropriate Gifts and hospitality can give rise to a Conflict of Interest or perceived conflict between personal interests and professional responsibilities, potentially undermining OICR’s reputation. Determining what is acceptable and what is unacceptable requires each OICR Individual to exercise good judgment and moderation and to seek approval if there is any doubt.

Accepting or offering any Gift or hospitality, regardless of value, that either makes the recipient feel obligated, or could be construed as a means to make the recipient feel obligated to start or continue a business relationship, is unacceptable and will be a breach of this policy. Acceptance of multiple Gifts from a third party such as a vendor, supplier or customer by one or several OICR Individuals may also be violating the spirit of this policy because it may be perceived as a means to make OICR feel obligated to start or continue a business relationship.

Modest and reasonable hospitality with business partners in the ordinary course of business, including occasional meals of reasonable expense, is generally acceptable. Hospitality will not be considered modest and reasonable if the hospitality leads to a sense or feeling of obligation or a perception of an obligation on the part of the recipient.

Business-related social events are acceptable provided that events are reasonable and modest in terms of value, both when viewed as a single event or as a total value over a period of one year, and cannot be construed as a bribe or a pay-off.

All expenses must be properly recorded in reasonable detail such that they accurately and fairly reflect the true nature and amount of the expense.

iii) Specific Gifts and Hospitality that are Prohibited

The following are examples of the types of activities or Gifts that may not be offered, given or received:

- One that is a violation of any laws or regulations;
- Cash, or anything equivalent to cash (such as Gift certificates, loans, stock, or stock options);
- Part of an agreement requiring anything in return for the Gift (even if the Gift is small in value or below \$100.00), i.e., "getting something for something";
- Sexually-oriented Gifts or materials that otherwise violate OICR's commitment to valuing diversity in the workplace;
- Anything that violates any of OICR policies or the policies of the recipient's organization; and/or
- Anything not recorded properly in OICR's accounting records (which in itself could raise other legal and ethical issues).

III) Guidelines relating to Enticement

The following are examples of certain activities that may raise suspicion about a person with whom OICR has done, or proposes to do, business:

- Insufficient, false, or inconsistent information provided by the person and/or reluctance by the person(s) concerned to provide any information requested for proper identification;
- Cash transactions, or requests that are not consistent with the business activities of the person;
- A request by a person to structure a transaction to evade normal record keeping and/or reporting requirements, or to structure it in a such a way that appears to have no legitimate business purpose;
- A person opens a number of accounts under one or more names and asks for payments to be distributed among those accounts or deposited in those accounts in small increments;

- Payments through a third party (other than a bank) that has no contractual relationship with OICR or transactions involving several individuals and companies where there is no apparent relationship;
- Payments for large amounts by way of money orders, travellers' cheques or cash;
- When there are hints or signs that the person is not acting on his or her own behalf, but is trying to conceal the true beneficial owner's identity;
- Transactions, where money or property is passed through a consultant or representative to a public official, to obtain certain government actions;
- Gifts or gratuities to government officials, political party officials, candidates for public office, customers or to their families;
- Extravagant hospitality to government officials, party leaders, customers or their families;
- Indirect payments to vendors, government officials, or their families; and/or
- Requests for unusually large retainers, or other fees.

IV) Guidelines relating to Use of Institute Assets

OICR's assets, whether in physical or intangible form, are to be used for OICR's legitimate business purposes and are intended to assist OICR Individuals in achieving their business goals. Damaged, misused or wasted assets impact OICR's operational and financial performance.

Good judgment and appropriate care must be taken by all OICR Individuals to ensure that OICR assets are not lost, damaged, misused or wasted. Institute assets should not be loaned to others, transferred, sold or donated without authorization (refer to policy on Removal of Surplus and End-of-Life Assets).

If any misuse of institute assets arises, OICR Individuals should immediately discuss the situation with their managers.

V) Principles relating to Outside Professional Activities of Research Staff

The following principles are those used by OICR in determining permissibility of Outside Professional Activities by Research staff, including those from which Research staff may derive supplemental income and/or equity capital:

- Research staff must be fully engaged in research, teaching and service to OICR and its partner agencies;
- Research staff receiving PHS/NIH funding do not hold an SFI as per section 4.2.1 which could directly and significantly affect the design, conduct, or reporting of PHS/NIH-funded research as judged by the OICR Conflict of Interest Committee;
- Research staff are required to use OICR resources appropriately;
- Research staff will maintain a significant physical presence in OICR's research laboratories; wherever applicable they must be accessible to students and staff under their supervision and be available to interact on a daily basis for 80 per cent of all business days during a calendar year (~200 business days), unless permitted to do otherwise;
- Outside activities and/or non-OICR projects in which research staff are engaged are not funded or supported by the tobacco industry (e.g., manufacturers, the Council for Tobacco Research or the Smokeless Tobacco Council or any other organization that acts on behalf of or is sponsored directly or indirectly by the tobacco industry).

Examples of Outside Professional Activities Requiring Approval

The following activities require written approval from the Conflict of Interest Committee:

- All paid professional activities;
- Non-paid activities that exceed the commitment within this policy;
- External management roles which require a significant time commitment;
- OICR scientists hiring and supervising students or other research staff for non-OICR activities;
- With regard to the involvement of any funds administered by OICR, any act relating to the hiring, supervising, or evaluating of, purchasing from, selling to, engaging in any commercial transaction with, conferring or denying any financial or commercial benefit to any member of the scientist's Immediate Family or a person with whom there exists, or has recently existed, an intimate personal relationship;
- With regard to the involvement of any funds administered by OICR, any research undertaken by a scientist for a company or organization in which an SFI is held by the scientist, any member of the scientist's Immediate Family, or any person with whom there exists, or has recently existed, an intimate personal relationship;
- Hiring OICR staff for external professional activities;
- A scientist who wishes to carry out any outside activities that involve the use of OICR facilities, supplies or staff; and
- A scientist who wishes to carry out external research using OICR administered funds.

VI) Guidelines Regarding the Reporting of Reimbursed or Sponsored Travel as an SFI for PHS applicants (including the NIH)

Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

Within the discretion afforded by the final rule, OICR has imposed a \$5,000 *de minimis* threshold for reimbursed or sponsored travel disclosures. Consistent with the requirements for other types of Financial Interests within the regulatory definition of an SFI, the *de minimis* threshold will apply to Reimbursed or Sponsored Travel when aggregated per entity.

Reimbursed or Sponsored Travel that surpasses the \$5,000 *de minimis* threshold must be disclosed as an SFI as per the procedures outlined in this policy and will be assessed accordingly.

Appendix C: Disclosure of Conflict of Interest

Form A

All OICR Individuals are required to acknowledge that they have received, read, and comprehend the terms of the policy by signing this disclosure form on commencement of employment and when changes occur.

Name: _____ Date: _____

Program: _____

I acknowledge that I have received, read and comprehend the terms of the Conflict of Interest Policy and Guidelines of OICR. In making this declaration I have considered not only my own circumstances but also those of my Immediate Family and/or any person with whom I have a close personal relationship as defined in the policy. I have given careful consideration as to whether any of the circumstances outlined in the Conflict of Interest Policy and Guidelines apply to me and could lead to a potential or perceived Conflict of Interest.

I recognize that I have an ongoing responsibility to bring to the attention of my manager any potential or existing Conflict of Interest so that a decision regarding permissibility or non-permissibility, and creation of a Conflict of Interest management plan, if applicable, can be made and I agree to be bound by that decision. I also agree that if there is doubt as to whether a potential Conflict of Interest exists that I will err on the side of disclosure and bring the facts forward to my manager. As an OICR Individual, I agree to be bound by the terms and conditions contained in the Conflict of Interest Policy and Guidelines and any amendments thereto.

I confirm as of the above date I have (check as applicable):

- a) _____ no Conflict of Interest.
 b) _____ a possible Conflict of Interest as described on Form B.

If you answered "no Conflict of Interest", your disclosure is complete; you do not have to submit Form B. Please sign and date the certification below.

If you answered "a possible Conflict of Interest as described on Form B" you must complete a separate Form B for each entity/organization with which you (or your Immediate Family or person with whom there exists or has recently existed an intimate relationship) have a Conflict of Interest to be disclosed.

OICR Individual's

Signature: _____ Date: _____

Manager's

Signature and

Printed Name: _____ Date: _____

Return completed form to Human Resources.

Form Title and Number: Conflict of Interest Forms (F- AD-GEN.102-01)

Associated Policy Title and Number: Conflict of Interest Policy and Guidelines (AD-GEN.102)

Template Created On: October 4, 2009

Last Modified: May 29, 2017

Disclosure of Conflict of Interest – Form B (Part I and Part II)

<p>INSTRUCTIONS</p> <ol style="list-style-type: none">1) Use separate disclosure forms for each entity/organization with which you (or your Immediate Family or person with whom there exists or has recently existed an intimate relationship) is involved giving rise to a potential Conflict of Interest.2) Part I is required for disclosure of all conflicts of interest. Part II is required for disclosure of Significant Financial Interests.3) You are required to include all information as requested on this form in addition to any other details that would enable you to make a full and complete disclosure.4) Return completed forms to OICR Human Resources.
--

Part I: Conflicts of Interest (for OICR Individuals disclosing a Conflict of Interest)

Name: _____ Date: _____

Program: _____

Total number of Part I forms submitted: _____

Total number of Part II forms submitted: _____

1. Name of entity / organization with which there is an existing or proposed relationship:

2. What is the nature of the work/activity or project?

3. What is your rationale for undertaking this work or activity?

4. What is the nature of the relationship? Check all that apply. For example, if you are currently a founder of and a consultant to an organization from which it is proposed that you would receive Gift funds, you would check both of the appropriate boxes under EXISTING and the "Gift" box under PROPOSED.

Form Title and Number: Conflict of Interest Forms (F- AD-GEN.102-01)
Associated Policy Title and Number: Conflict of Interest Policy and Guidelines (AD-GEN.102)
Template Created On: October 4, 2009
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Relationship	EXISTING	PROPOSED
Founder		
Employee/Executive Position		
Board Member		
Scientific Advisory Board		
Consultant		
Stock or Ownership Interest		
Gift		
Reimbursed or Sponsored Travel		
Sponsored Research Project		
Licensors of Technology		
Clinical Trial		
Family Member		
Other:		

5. Explain how you intend to separate any potential conflicts between your OICR responsibilities and your disclosed activities with the commercial entity.

6. Please list other activities or relationships that have already been approved this year or that are continuing from any previous year.

7. If you checked EXISTING OR PROPOSED for Gift, explain how you intend to use the Gift.

8. If you checked EXISTING or PROPOSED for Reimbursed or Sponsored Travel, please provide the following information:
Purpose of the trip:

Sponsor/Organizer:

Destination:

Duration:

For Research Projects (questions 9-13)

9. If you checked either EXISTING or PROPOSED for any research project, then answer the following applicable questions:
- a. Provide the title of the project and a description of the sponsored research project.

 - b. Indicate the source(s) of funding for the project?

 - c. Is the sponsored research being conducted for regulatory approval (indicate yes or no) or does it use a technology licensed to the sponsor? Please explain.

 - d. Is the clinical trial testing your own invention or the company's own products? Please explain.
10. What is your role in the disclosed activity or relationship (e.g., principal investigator of study, co-investigator, organizer of Continuing Medical Education, etc.)?
11. Will the disclosed activity involve use of OICR facilities and/or supplies? What is the rationale and scope of use?
12. Who else will be involved in the activity (e.g., students, postdoctoral fellows, etc.) and how?
13. How might the disclosed relationship affect your OICR research (including the research projects of your students and postdoctoral fellows), teaching and/or other responsibilities at OICR? Specify also the time commitment required by the disclosed activity or relationship.

Significant Financial Interest

14. Does the conflict being disclosed involve Significant Financial Interest as defined in OICR's Conflict of Interest Policy and Guidelines? If your answer is "Yes" you must complete Part II of this form. If your answer is "No" your disclosure is complete; you do not have to complete Part II. Please sign and date this form.

_____ YES

_____ NO

Part II: Significant Financial Interests (for OICR Individuals disclosing a Significant Financial Interest)

I am disclosing the following Significant Financial Interests as per OICR's Conflict of Interest Policy and Guidelines and attaching supporting documentation that identifies the business entity involved, the nature and amount of the interest (check all that apply):

["Significant Financial Interest" (refer to Conflict of Interest Policy and Guidelines for full details) refers to

- receipt of greater than \$5,000 aggregate remuneration from any publicly traded company in 12 months prior to the date of disclosure; remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
- receipt of greater than \$5,000 aggregate remuneration from any non-publicly traded company or equity holding of any amount;
- receipt of intellectual property rights, royalties from such rights, agreements to share in royalties from such rights; or
- where the OICR Individual has actual knowledge of Immediate Family having met one or more of the above criteria.]

Financial Relationship	Amount of interest (\$ or %)	Individual(s) involved in financial relationship (indicate Self, Family Member, Other Party in a Significant Relationship)
Consultant		
Remuneration (e.g., employee, executive or Board position)		
Equity interests (e.g., stocks, stock options, or other ownership interest)		
Honoraria		
Gift		
Licensors of Technology (e.g., intellectual property rights and royalties from such rights)		
Reimbursed or Sponsored Travel		
Research Project Sponsorship		
Other (e.g., paid authorship, other):		

Form Title and Number: Conflict of Interest Forms (F- AD-GEN.102-01)

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Certification:

I certify that the answers to my declaration in Part I and Part II are accurate and truthful to the best of my knowledge.

I acknowledge and OICR may have to share the information publically, if requested, and by signing this form I authorize OICR to release this information as and when required.

I acknowledge my ongoing obligation to inform OICR of any changes in activity status as required by all OICR Individuals, as well as:

- within 30 business days of a new Significant Financial Interest; and
- at the time of applying for PHS/NIH funding (as applicable).

I understand that any potential Financial Conflicts will be reviewed and managed in order to access research funding and I agree to fully participate in the development and implementation of any necessary Financial Conflict of Interest management plans recommended by the OICR Conflict of Interest Committee.

OICR Individual's
Signature and Printed
Name:

_____ Date: _____

Manager's Signature and
Printed Name:

_____ Date: _____

Manager's
Comments:

Return completed form to Human Resources.