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Authority (Title)			Policy Owner (Title)			
Executive Team			Chief Executive Officer			
Required Reviewers (Titles)						
Executive Team Program Leaders		3		Conflict of Interest Committee		

Please refer to the **glossary** for terms and definitions.

1.0 PURPOSE

- 1.1 ICES is a publicly funded, not-for-profit research institute, whose mission is translating data into trusted evidence that makes policy and health care better and people healthier. To meet its mandate, ICES must produce, and be perceived as producing, trusted and excellent research that is in the public interest.
- 1.2 ICES must protect its reputation to maintain continued public trust, by ensuring that the work done at or under the auspices of ICES by those in the ICES community reflects ICES' mission.
- 1.3 ICES must ensure that all members of its community (see "Scope" in Section 2.0) act in ways that advance ICES' mission and enhance ICES' reputation. Actual, perceived, or potential Conflicts of Interest ("COI") in the ICES community can harm ICES' reputation and ultimately damage the public's trust in ICES.
- 1.4 The purposes of this **Policy** are to ensure ICES maintains a robust framework to avoid, minimize, and effectively manage actual, perceived, or potential **COIs**.

2.0 SCOPE

- 2.1 This **Policy** applies to **ICES Agents**, including:
 - 2.1.1 ICES Employees;
 - 2.1.2 Site Employees, when the individual is acting as an ICES Agent;
 - 2.1.3 ICES Scientists;
 - 2.1.4 ICES Students:
 - 2.1.5 ICES Trainees (ICES Post-Doctoral Trainees, ICES Fellows, and ICES Visiting Scholars);
 - 2.1.6 Third Party Service Providers ("TPSPs");



- 2.2 This **Policy** also applies to individuals applying for employment or an appointment at ICES. At the time of their application, they must declare **COIs** at present and for the prior three years.
- 2.3 This **Policy** is of particular relevance to:
 - 2.3.1 Individuals who conduct Research and/or Statistical Analysis and disseminate findings, who, by the nature of his/her position, responsibilities or otherwise, interacts with suppliers, potential suppliers, or any organization/individual that has or may have business dealings with ICES who may be directly or indirectly affected by Research and/or Statistical Analysis conducted at ICES;
 - 2.3.2 ICES Employees that, by virtue of their position, responsibilities, and/or expertise have marketable skills of interest to others, such as external research teams, organizations, and companies.

3.0 ROLES AND RESPONSIBILITIES

- 3.1 Chief Executive Officer ("CEO")
 - 3.1.1 Acts as Chair of the Conflict of Interest Committee and reviews all ICES agent declarations. CEO has discretion to review and clear declarations, and determines which declarations will be referred to COI Committee for further review and consideration. Ensures that the decisions of the COI Committee and communicated to the individual who made the declaration, and to others in the ICES community as necessary to ensure adequate mechanisms to enforce decisions are in place.
- 3.2 Chair of the Board of Directors
 - 3.2.1 [Description] Reviews the COI declarations of the CEO and has discretion to clear declarations. If needed, the Chair may refer the declaration to the Board Governance and Nomination Committee for review and consideration.

4.0 DETAILS

4.1 Definitions

4.1.1 Conflict of Interest ("COI")

- a. Refers to any situation where there is a potential divergence between an individual's interests and his or her obligations to ICES. A COI may be actual, perceived or potential.
- b. A COI exists when it can be reasonably determined that an Individual Financial
 Interest or Benefit (see definition below) or Family Financial Interest or Benefit (see
 definition below) could directly affect (or reasonably be perceived to affect):
 - i. the research question, design, conduct, analysis or reporting of an ICES Project;
 - ii. an ICES action (e.g., business decisions or transactions, prioritizing of ICES **Projects**, resources, collaborations, or partnerships);
 - iii. ICES' business, mission, or reputation;

4.1.2 Individual Financial Interest or Benefit



- a. This is interpreted broadly, and means anything relating to an individual's private interests (regardless of monetary value) now or in the future. It includes, but is not limited to, money, stocks, stock options, goods, speaker's fees, stipends and honoraria, gifts (including offers of products or services), bonus or milestone payments, equity interest and the opportunity to receive a financial interest or benefit received either directly or indirectly.
- b. An Individual Financial Interest or Benefit does not necessarily need to be monetary (e.g., access to research support) and it may be provided as a direct or indirect benefit. That is, the benefit may be directly given to the individual or it may be given to a third party/entity for direct benefit to the individual (e.g., flowed through a research account, department, or through a professional corporation).
- c. An Individual Financial Interest or Benefit excludes income in the form of wages and salaries paid by ICES and by other public institution (e.g., government including OHIP, publicly-funded research institutes and peer-reviewed granting agencies).

4.1.3 Family Financial Interest or Benefit

- a. Defined the same as Individual Financial Interest or Benefit except this refers to financial interests or benefits received directly or indirectly by a member of the individual's immediate family.
- b. An individual's immediate family is defined:
 - i. A spouse/common-law partner;
 - ii. Parents (step and in laws);
 - iii. Siblings (including step and in laws); and
 - iv. Children (including step and in laws).
- 4.2 Managing COIs includes any condition or restriction applied by ICES to manage COIs.
 Management Plans are developed in consultation with the individual but are ultimately determined by ICES at its sole discretion.
- 4.3 Guiding Principles
 - 4.3.1 All ICES decisions for addressing **COI** situations will be guided by ICES' obligation to maintain the public's trust. No **Research**, **Statistical Analysis**, or other ICES activities, including commercialization activities relating to **ICES Intellectual Property ("ICES IP")**, will be undertaken with unmanaged **COIs**.
 - 4.3.2 ICES may determine a **COI** cannot be adequately managed in cases where:
 - a. the individual will not or cannot comply with the Management Plan;
 - b. the Management Plan cannot be determined or enforced; or
 - c. the ICES resources needed to manage the situation are deemed excessive by ICES.
 - 4.3.3 ICES embraces transparency and accountability in its processes for dealing with **COI** situations and will ensure consistent application of this **Policy**.
 - 4.3.4 ICES may make a summary of all **COI** declarations and **Management Plans** publicly available, such as by posting on ICES' public website, if it decides this is prudent for good governance.



- 4.3.5 Employment with and/or ongoing appointment to ICES requires full and accurate disclosure of actual, perceived, and potential **COIs** annually, as well as ad-hoc **COI** disclosure as soon as they become known to the individual.
- 4.3.6 ICES requires accuracy and completeness in **COI** declarations. ICES may undertake random or selected audits of an individual's **COI** declarations. If ICES receives additional information about **COIs** beyond what was disclosed in the individual's **COI** declaration, ICES will review these additional **COIs** as part of this **Policy**.
- 4.3.7 Decisions rendered under this **Policy** are to be made by the CEO, or delegate(s), except for decisions concerning the CEO. Decisions regarding **COI** declarations made by the CEO are the responsibility of the Chair of the Board of Directors.

4.4 Prohibited Activities

- 4.4.1 It is not possible to provide an exhaustive list of all prohibited activities. The following situations serve as examples:
 - a. Using one's position, influence, or authority in ICES for **Individual Financial Interest** or Benefit or Family Financial Interest or Benefit.
 - b. Using ICES resources, such as Technology Resources and ICES Information, including but not limited to ICES Data and ICES IP, gained through employment, appointment, or affiliation with ICES for Individual Financial Interest or Benefit or Family Financial Interest or Benefit;
 - Allowing a sponsor or stakeholder of ICES (or of Research and/or Statistical
 Analysis) the right to veto or change the design, analysis, interpretation or reportage of
 findings or its dissemination (an opportunity to comment is allowable so long as it does
 not exceed 30 days);
 - d. Guaranteeing to anyone, including a sponsor or a stakeholder of ICES (or of **Research** and/or **Statistical Analysis**), a specific scientific finding;
 - e. Conducting research or statistical analysis with, or for, another entity which uses ICES
 Information, including but not limited to ICES Data and ICES IP, and/or Technology
 Resources without ICES approval;
 - f. Accepting money, Individual Financial Interests or Benefits, or Family Financial Interests or Benefits from a for-profit entity for research or statistical analysis which uses ICES Information, including but not limited to ICES Data and ICES IP, and/or Technology Resources;
 - g. Posing a research question or designing, analyzing, interpreting or reporting an ICES Project in order that it will or may produce an Individual Financial Interest or Benefit or a Family Financial Interest or Benefit;
 - Signing a contract or agreeing to an undertaking on behalf of ICES that is contrary to this **Policy**;
 - Asking an ICES Employee to undertake non-ICES work or activities that contribute to one's Individual Financial Interest or Benefit, or a Family Financial Interest or Benefit;



- j. Accepting, buying, or seeking out the ownership of stock options or stock (excludes stock or stock options that arise from passive investment adviser-led portfolios, , including the Healthcare of Ontario Pension Plan (HOOPP)) in a for-profit company (either publicly traded or privately held) that is related to a drug, technology, or health service that ICES is studying or may reasonably do so in the future;
- k. Being employed by, acting as a Director of, or otherwise receiving an Individual Financial Interest or Benefit or a Family Financial Interest or Benefit from a forprofit company that is related to a drug, technology, or health service that ICES is studying or may reasonably do so in the future;
- I. Being a member of a Speakers Bureau (or equivalent speaker arrangement) for a forprofit company or entity;
 - i. A Speakers Bureau is a system used by for-profit entities which involves hiring, training, and rewarding/paying speakers to deliver academic presentations to clinical or other decision-makers to persuade the audience to use or prescribe their product. Presentations are based on materials prepared for them by the for-profit entity, and even if speakers can revise the presentation, the final control of the content rests with the for-profit entity.
- m. Providing educational or research talks for a for-profit company or entity where the individual does not create the content and is not able to exercise academic control over the content and its delivery.
 - Note: even if the above conditions are met it may still be prohibited activity if these
 particular features are not transparent to ICES or the audience, and/or if it otherwise
 compromises the public's trust in ICES;
- n. Acting as a consultant or advisor for a for-profit company or entity and providing non-scientific general or specific business advice, regardless of the dollar amount involved;
- o. Acting as a consultant or advisor for a for-profit company or entity without having a written agreement or written contract consistent with this **Policy**. Such an agreement/contract should be for a fixed-term (without any automatic renewal clauses) and explicitly set out expectations for each of the parties with no further obligations after the termination date. The consultant or advisor role must not include business or market advice and instead it should involve providing scientific and/or clinical advice specific to one's area of expertise. All contracts must be submitted to ICES at the time of **COI** declaration;
- p. Taking any administrative action (including, but not limited to, hiring of staff, procurement of materials, managing contracting, selecting equipment or supplies) within or on behalf of ICES with an organization/individual where an individual (or family member) stands to gain an Individual Financial Interest or Benefit or a Family Financial Interest or Benefit (or appears to be doing so);
- q. Offering or accepting an Individual Financial Interest or Benefit or a Family Financial Interest or Benefit in order to influence business transactions in which ICES is involved;



r. Using ICES Information, including but not limited to ICES Data and ICES IP, and/or Technology Resources for any non-ICES activity in a manner not permitted by Policies, Standards, and Procedures.

4.5 Allowable Activities

- 4.5.1 Certain activities are allowable if these activities meet the following criteria:
 - a. They are independent from ICES;
 - b. They do not use ICES Information, including but not limited to ICES Data and ICES IP;
 - c. They do not use Technology Resources; and
 - d. They do not compromise, or be reasonably seen to compromise, ICES' reputation or mission.
- 4.5.2 Even when an activity is allowed, the **Policy** requires that these activities still be disclosed to ICES as part of the **COI** disclosure process.
- 4.5.3 It is not possible to provide an exhaustive list of all allowable activities. The following situations serve as examples.
 - Participating in a properly constituted Independent Data Safety Monitoring Board for a
 particular trial or trials sponsored by a non-profit or for-profit pharmaceutical, device, or
 other health products company;
 - Being a member of the Steering Committee, Publishing Committee, or Coordinating Committee for a particular trial or trials sponsored by a non-profit or for-profit pharmaceutical, device, or other health products company;
 - c. Conducting research directly or through another institution for a for-profit entity (e.g., conducting an industry-sponsored clinical trial which has a research agreement between the sponsor, the individual, and his or her other institution) where the activity does not compromise ICES' reputation for independence and integrity
 - d. Providing an acceptable service (e.g., scientific and/or clinical advice and not business advice) to a for-profit company or agency with an acceptable written agreement or contract concerning a drug, technology (including medical, health or healthcare computer, software or other related applications), or health service that ICES could reasonably study in the future, and that is not in conflict with (and not perceived to be in conflict) one's ICES work. Such an agreement/contract should be for a fixed-term and explicitly set out expectations for each of the parties with no further obligations after the termination date. All contracts must be submitted to ICES at the time of the COI declaration;
 - e. Creating or developing (or participating in the creation or development of) a not-for
 profit medical, health or healthcare application (app) that is not in conflict with (and not
 perceived to be in conflict) one's ICES work and does not compromise ICES' reputation
 for independence and integrity;
 - f. Participating in an external committee with the authority to review, approve or fund/reimburse a drug, technology, or health service as part of a government program (e.g., a federal or provincial health technology assessment review panel).



- g. Providing clinical/scientific advice in private sector-funded Third Party Research Projects. ICES Core Scientists and ICES Adjunct Scientists may participate in such studies only on a very limited basis and only when specific conditions are met.
- 4.6 Payment and benefits to individuals for allowable activities
 - 4.6.1 It is acceptable to receive reasonable honorariums, stipends, payments, or small gifts paid directly to the individual from a for-profit or non-profit company or entity for providing a specific allowable activity/service as long as these, by their frequency or amount (singly or accumulated) do not affect (or reasonably be perceived to affect) an individual's work at ICES or ICES' mission or reputation.
 - 4.6.2 Individuals may not receive remuneration or financial benefit directly or indirectly from forprofit companies or entities for educational talks, advisory/consultative roles, and activities that exceed the annual dollar value limit as determined by ICES from time to time.
 - a. The current total allowable limit is \$15,000 per annum cumulative total for all such activities.
 - 4.6.3 There are two allowable activities which are excluded from the \$15,000 per annum limit (these must still be declared to ICES):
 - a. Participating in an Independent Data Safety Monitoring Board as long as it involves an independent group of experts who are responsible for monitoring a study by reviewing data and who have no professional or financial **COIs** with the research project, investigators, or sponsor/funder of the research;
 - b. Participating in an external committee with the authority to review or approve a drug, technology, or health service as part of a government program (e.g., a federal or provincial health technology assessment review panel).
 - c. Other scientific advisory activities or consultations that relate to ICES work that is expressly pre-approved by the COI committee prior to the conduct of the work, and subject to terms and conditions that may be established by ICES from time to time.

4.7 Declaring Conflicts of Interest

- 4.7.1 It is the responsibility of all ICES community members to whom this **Policy** applies (see "Scope" in Section 2.0) to report actual, perceived, or potential **COIs**.
- 4.7.2 ICES encourages disclosing any activity where the individual is uncertain whether it may represent a perceived, potential, or actual COI. Even if an individual believes an activity falls within the examples of allowable activities, the individual is required to make a declaration.
- 4.7.3 Nothing in this **Policy** shall be interpreted to mean that there are no obligations or duties to report the same **COI** elsewhere. For example, individuals are reminded that **Research Ethics Boards**, journals, and other public institutions will require declarations of **COIs**.
- 4.7.4 All individuals will:
 - a. Provide full and accurate disclosure of actual, perceived, or potential COI situations annually and as these become known to the individual and in advance through ad-hoc disclosures;



- b. Disclosures must be made using current standard ICES forms and tools (e.g. online application or paper form outlined in <u>Appendix A</u>) within specified deadlines;
- c. Provide all necessary documentation at the time of disclosure (e.g., copy of executed agreements, invitation letters) and additional documentation and information that may be requested by ICES;
- d. Respond as soon as reasonably possible to ICES requests for disclosure or details;
- e. Report in good-faith;
- f. Seek clarification from the CEO (or from the Chair of the Board of Directors if the CEO) about what is or might be seen as **COI** situations if in doubt;
- 4.7.5 The CEO will declare his or her own actual, perceived, or potential **COIs** to the Chair of the Board of Directors in writing at the earliest opportunity.

4.8 Reviewing and Managing Conflicts of Interest

4.8.1 Reviewing COI declarations

- a. An ICES Conflict of Interest Committee will review all COI declarations other than that of the CEO (which is reviewed by the Chair of the Board of Directors). Members are appointed by the CEO and the committee acts in an advisory capacity to the CEO.
- b. The CEO (or his/her delegate) may determine which declarations require review by the entire committee. The CEO and COI Committee may request additional information and documents, contact other parties relevant to the declaration, obtain additional information, and meet with individuals reporting a COIs in order to make a determination regarding a COI declaration.
- c. The review will determine if each declared activity represents a COI and, if so, determine the details of any required Management Plan. The CEO or his/her delegate will discuss all decisions regarding declared activities with the affected individual along with the Management Plan, if applicable. For individuals applying for appointment to or employment with ICES, ICES reserves the right under this Policy to deny such applications based on the presence of COIs.
- d. Management Plans are binding on the individual and will vary depending on the nature of the COI and the circumstances. The review decisions are final and binding. They will be communicated to the individual in writing and included in future appointment and/or employment letters as required.
- e. COI declarations for the CEO will be reviewed by the Chair of the Board of Directors. The Chair may meet with the CEO upon receipt of a COI report. The meeting will be for information gathering and to explore more fully the actual, perceived, or potential COIs. The Chair will determine if the activity represents a COI and, if so, determine the details of any required Management Plan. All decisions rendered by the Chair regarding actual, perceived, or potential COIs by the CEO shall be final and binding.

4.8.2 Confidentiality

a. The CEO (or the Chair of the Board of Directors) may consult in confidence with others inside and outside of ICES for the purposes of reviewing or managing COIs. The CEO may reveal in confidence necessary information regarding COI determinations and Management Plans only to those ICES Agents or outside parties where, in the opinion



- of the CEO, in consultation with the Chief Privacy and Legal Officer ("CPLO"), it is required for the effective implementation of the **Management Plan**, and/or to protect ICES' reputation and mission.
- b. Information gathered in the COI disclosure, the Management Plan, and discussions and notes about these documents and the COIs shall be considered ICES Confidential Information. ICES may make a summary of all COI declarations and Management Plans publicly available, such as by posting on ICES' public website, if it decides this is prudent for good governance. For each ICES Scientist, a statement is published declaring whether or not each has an "ICES-relevant COI". More information, including the presence of any Management Plan, may be made available upon request, including to the public.

4.8.3 Penalties

a. Breaches of this **Policy** may be cause for reprimand, limitations of ICES privileges, activities or work, dismissal or otherwise loss of employment, appointment or affiliation with ICES. Penalties for breach of this **Policy** will depend upon the nature and severity of the **COI** and the circumstances of the individual in each case. Breaches of this **Policy** at the time of application for appointment/employment will likely result in denial of an appointment/employment. All decisions regarding penalties shall be made by the CEO and are final and binding. The Chair of the Board of Directors shall make decisions relating to the CEO's **COIs**.

5.0 RELATED DOCUMENTATION

- 5.1 Policies
 - 5.1.1 Privacy Incident and Privacy Breach Management Policy
 - 5.1.2 Discipline and Corrective Action in Relation to ICES Data Policy
 - 5.1.3 Termination or Cessation of Employment or Contractual Relationship in Relation to ICES Data Policy
 - 5.1.4 Privacy and Security Audit Policy
 - 5.1.5 Ongoing Review of Privacy and Security Policies, Standards, Procedures, Practices, and Exceptions Policy
 - 5.1.6 Change Management Policy
- 5.2 Standards
 - 5.2.1 Cybersecurity Incident Management Standard
- 5.3 Procedures
- 5.4 Guidelines
- 5.5 Tools
 - 5.5.1 **Conflict of Interest** declaration form

6.0 TRAINING AND COMMUNICATION



- 6.1 **Policies, Standards,** and **Procedures** are available on the **ICES Intranet**.
- 6.2 This **Policy** and any related **Standards** and/or administrative **Procedures** are communicated to all **ICES Agents** across the **ICES Network** during onboarding and on a yearly basis. **Policy** awareness is also supported and promoted by the **Policy Owner**.
- Once new **Policies** and **Standards** are published to the **ICES Intranet**, they are communicated to **ICES Employees** on the **ICES Intranet**.

7.0 COMPLIANCE AND ENFORCEMENT

- 7.1 ICES Agents must comply with all applicable Policies, Standards, and Procedures.
- 7.2 ICES Agents must notify a Privacy Subject Matter Expert ("SME") or Security SME at the first reasonable opportunity if they breach or believe there has been a breach of ICES' privacy and security Policies, Standards, or Procedures, in accordance with the Privacy Incident and Privacy Breach Management Policy and the Cybersecurity Incident Management Standard, as applicable, and as set out in the framework posted on the Privacy and Legal Office/Cybersecurity site on the ICES Intranet.
- 7.3 All other violations under ICES privacy and security **Policies, Standards**, and **Procedures** may be subject to a range of **Disciplinary Actions** in accordance with the *Discipline and Corrective Action in Relation to ICES Data Policy* and the *Termination or Cessation of Employment or Contractual Relationship in Relation to ICES Data Policy*.
- 7.4 Compliance is subject to audit in accordance with the *Privacy and Security Audit Policy*.

8.0 EXCEPTIONS

8.1 Any exceptions requested pursuant to this **Policy** must be in accordance with the *Ongoing Review* of *Privacy and Security Policies*, *Standards*, *Procedures*, *Practices*, and *Exceptions Policy* and the *Change Management Policy*.



Appendix A

CONFLICT OF INTEREST (COI) DECLARATION FORM

For declaring COI and no COI Annually and Ad Hoc (and if asked, at the time of Appointment renewal)

Name:		(Please print)
Date:		
Contact Inform	nation: Email and phone number	
Type of Appoi	ntment	
•] Annual Disclosure []] Appointment Renewal []	Ad Hoc Disclosure [] New Appointment New ICES Agent
Instructions:		
Please comp	lete only Section 1 if you have NO	Conflicts of Interest to declareOR-
Please comp	lete Section 2 if you have Conflicts	s of Interest to declare (actual, perceived or potential).
	the first time you are completing to for the past three (3) years.	he ICES COI declaration form, please report all COI (or
Section 1		
questions cond Conflicts of Int Conflicts of Int	cerning it have been answered. I a terest to disclose for the period terest for this year, nor do I have a conflicts of Interest arise, I will ma	have received orientation to this Policy, and all my m declaring that I have no actual, perceived or potential to I do not anticipate having any ny undeclared Conflicts of Interest from the past 12 ake an ad-hoc declaration to the CEO's office by emailing
	(Signature).
	([Date or Fiscal Year Covered)



Section 2

I have read the ICES Conflict of Interest Policy. I have received orientation to this Policy, and all my questions concerning it have been answered. I am declaring that I have Conflict(s) of Interest (actual, perceived or potential) to disclose for period to If any additional Conflicts of Interest arise, I will immediately notify the Office of the CEO by emailing coi@ices.on.ca.					
Below is a listing of the Conflicts of Interest I am dec previously reported).	laring including those for the past 12 months (if not				
	_(Signature)				
	_(Date or Fiscal Year Covered)				



For Confidential Office Use Only:

[] I have reviewed this COI declaration form and no further action is needed at this time.
[] I have reviewed this COI declaration form and will meet with the individual.
Signature (CEO)



Appendix B Frequently asked questions - FACULTY

1. Conflicts of interest are any situations where there is a potential divergence between an individual's private interests and his or her obligations to ICES. What does "obligations to ICES" mean?

All those in the ICES community have obligations to ICES, which is defined by the work they do under the auspices of the institution. ICES is a publicly funded, not-for-profit organization that has a mission of translating data into trusted evidence that makes policy and health care better and people healthier. To meet its mandate, ICES must produce, and be perceived as producing trusted and excellent research that is in the public's best interest and it must protect its reputation to ensure continued public trust. ICES' reputation is dependent on it. The work done under the auspices of the institution by those in the ICES community must reflect ICES' mission. Therefore, one's obligations to ICES are broadly defined and includes ICES' mandate to ensure the public's best interest and ensure continued public trust.

ICES mission and reputation includes the work you do under its auspices. When reviewing conflict of interest declarations, the CEO will consider, among other things, whether a perceived, potential or actual conflict of interest situation relates directly (or be reasonably seen to relate directly) to the individual's ICES research or research program. See the definition of Conflict of Interest for other considerations. All members of the ICES community must make fulsome declarations and the CEO will determine if it is a conflict of interest or not, taking into consideration the individual's ICES research or research program as well as the other considerations.

2. What is the timeframe for the Conflict of Interest disclosure?

All those in the ICES community who have a current appointment must make a Conflict of Interest declaration annually and during the year for any new material conflicts of interest situations as they become known and in advance (ad hoc declaration). The annual declaration should include any previously declared conflicts of interest that are still relevant, as well as any new ones. The ad hoc declaration only needs to include information about the new conflicts of interest situations.

Those individuals being considered for a new appointment must declare any current and past conflicts of interest in the current and the three fiscal years preceding the year of appointment application (e.g., an applicant in FY2023 would report any COIs between April 1, 2020 and March 31, 2024).

3. What do I do if I'm not sure about the need to declare an actual, perceived or potential conflict of interest situation?

Since it is the responsibility of all those in the ICES community to make a full and accurate disclosure of actual, perceived and potential conflicts of interest situations, individuals should err on the side of caution and make the disclosure. Any questions or ambiguities can be brought to the attention of the CEO.

4. The Policy says that ICES may make a summary of all COI declarations and management plans associated with those in the ICES community publicly known if it decides this is prudent for good governance. Will my name be associated with that disclosure?



Yes. Since 2017, we have been making information on scientist COIs publicly available. We now publicly state the individual has not declared any "ICES-relevant COIs" or that they have ICES-relevant COIs. Additional information, including any management plan(s), will be made available upon request. This is an important step and shows transparency at ICES, and protects the reputation and credibility of ICES scientists and the institute.

5. The Policy says that I can consult or act in an advisory capacity to a for-profit company or agency under certain conditions. It must involve providing scientific and/or clinical advice (and not business or market advice) and there must be a written agreement/contract for a fixed term that explicitly sets out expectations for each of the parties with no further obligations after the termination date. The work must not be otherwise prohibited, and if the work is independent to ICES, must not use ICES data, name, logo, or business tools nor compromise (or be seen to reasonably compromise) ICES reputation or mission. I have to declare the activity and it is possible a Management Plan may be needed. What does "compromise ICES reputation or mission" mean here? What is a "fixed term"?

Conflict of interest is any situation where there is a potential divergence between someone's private interests and his or her obligations to ICES. As stated in FAQ #1, one's obligation to ICES includes the work one does under the auspices of ICES. Therefore, if the private interest (individual financial interest or benefit or family financial interest or benefit) is directly related to one's ICES research this could make the activity prohibited. In terms of ICES' mission or reputation, if the consulting or advisory work negatively impacts on ICES being able to produce trusted and excellent research that is in the public's best interest and maintain continued public trust it would make the activity prohibited. If the activity is not directly related to one's ICES research, the CEO will consider, among other things, the amount of money received as that could impact of ICES' reputation (i.e. more than \$15,000 cumulative total per year for all such activities).

A fixed term contract is one that sets out expectations for each of the parties with a termination date (with no further obligations) and requires signatures. This contract must be submitted to ICES with your COI Declaration Form. ICES will review the agreement to ensure it is independent to ICES, and, among other things, does not involve ICES data, name, logo or business tools. ICES will need to review the nature of the work to satisfy itself the service provided is not in conflict with your research and does not compromise (or be perceived to compromise or have the potential to compromise) ICES reputation and mission. Particularly if there is more than one fixed term contract (regardless of whether it is with the same entity or not), ICES will consider the total annual remuneration as well.

6. Is it acceptable for me to hold stock or stock options? Do I have to declare them?

If you or your Family member receive money from investment vehicles, such as mutual funds or retirement accounts, this is not considered a conflict of interest as long as you do not directly control the investment decisions made in these investment vehicles. In these cases, you do not have to declare them. An example would be if you have a RRSP and have an investment adviser who manages your portfolio and you do not directly manage what stocks/options are purchased. If you agree to various types of investments based on your risk tolerance profile, this does not mean you directly control the investment decisions.

However, if you or your Family member has control over the investment decisions or if you have stock or stock options that you seek out or accept from a company (e.g. start up company that provides you with



stock instead of payment), regardless of whether they are biomedical in nature or not, then this is different. You have to declare stock and stock options if it impacts on your obligations to ICES (see FAQ #1) or if it could directly affect (or reasonably be perceived to affect) ICES' mission or reputation (see FAQ #2), ICES core business, an ICES action, or the research question, design, conduct, analysis or reporting of a study. However, sometimes it is difficult to determine whether there is a conflict of interest and therefore you will want to err on the side of caution and seek consultation from the CEO or disclose it on your declaration form. If the stock or stock options are biomedical in nature (e.g., device company, pharmaceutical company) then you should declare these stocks and stock options as you have an individual financial benefit and ICES will need to consider, for the individual case, if it could directly affect (or reasonably be perceived to affect) your research program, an ICES action, or core ICES business, mission or reputation.

7. I have ownership interest or am employed by a company which relates or could be perceived to relate to my ICES research, research program or the work of ICES. Should I still declare them?

Yes, you should declare this as you have an individual financial benefit and ICES will need to consider, for the individual case, if it could directly affect (or reasonably be perceived to affect) your research program, an ICES action, or core ICES business, mission or reputation.

8. I receive financial benefits from several pharmaceutical companies. I think this reduces my conflict of interest situation because I have a relationship with several such companies rather than with just one. Is this taken into consideration when my conflict of interest declaration is reviewed?

Regardless of whether you receive a financial benefit from one, several or many pharmaceutical companies, there could be conflicts of interest situations because of the work you do under the auspices of ICES and because of ICES' reputation or mission. Receiving a financial benefit from one, as opposed to several, pharmaceutical companies does not increase or decrease the conflict of interest situation as it is situation-specific (i.e., depends on the work that you do under the auspices of ICES and ICES' reputation and mission).

The ICES COI policy says it is prohibited to conduct research with, or for, another entity without ICES approval which uses ICES data, name, logo or business tools. Research that is funded in whole or in part by industry or other non-public source may be permissible only if certain conditions are met. Given the wide variation in circumstances for such funding, each must be reviewed for approval by the ICES CEO on a case-by-case basis. Contact the CEO's office for further detail.

9. I am involved with, or have a financial interest in, the commercialization of an algorithm or app based on research conducted using ICES data or resources, or that relates to research conducted using ICES data or resources. Do I need to declare that?

Yes. This could create a potential, perceived or actual COI as it may create for you an individual financial benefit associated with research at ICES. Such arrangements should be declared as a potential COI, as ICES will need to consider, in each case, if it could directly affect (or reasonably be perceived to affect) your research program, an ICES action, or core ICES business, mission or reputation.

10. The Policy says that I can participate, if nothing would otherwise make them prohibited activities, in a properly constituted Independent Data Safety Monitoring Board. What does "Independent" mean? I



know I have to disclose it to ICES (and a Management Plan may be needed), but it isn't clear what documentation ICES needs to decide if it is an independent Board.

You can participate on a properly constituted Independent Data Safety Monitoring Board as long as it is independent to your research and ICES, does not use ICES data, name, logo or business tools and does not compromise, or be reasonably seen to compromise, ICES reputation or mission. "Independent" means the group of experts on the Board are unaffiliated or arms-length from the researcher whose study is the subject of the Data Safety Monitoring Board, the research project, and the research sponsor or those who could gain financially from the research results. Independence is important for actual and perceived patient/participant safety and well-being. In the case of a for-profit device or pharmaceutical company or other health product company, ICES will need a copy of your agreement with the sponsor of the Independent Data Safety Monitoring Board.

11. Some of the potential conflicts of interest situations I have are not directly related to my ICES work, but to my other place of employment (e.g., hospital, university, not-for profit organization). Do I have to disclose them to ICES?

This question suggests that the potential conflict of interest situation does not directly affect (or reasonably be perceived to affect) the research question, design, conduct, analysis or reporting of a study being conducted under the auspices of ICES. However, someone in the ICES community could still be in a conflict of interest situation if that situation could affect an ICES action or core ICES business, mission or reputation. For example, if someone in the ICES community has teaching engagements sponsored by a for-profit organization, that information could potentially still be relevant to ICES even if it is not directly related to the research being conducted by the individual appointed or employed by ICES. You should err on the side of caution and disclose them to ICES or you can consult with the ICES CEO.

12. I am on advisory committees and I am a consultant for various non-profit organizations that are health related. Do I need to declare these given that they are not for profit (even if unpaid)?

If it creates or may create an Individual Financial Interest or Benefit or a Family Financial Interest or Benefit then is must be declared. The issue is not whether the organization is for profit or not, but rather one's private interests.

If it's unpaid work (and no opportunity to receive a financial interest or benefit directly or indirectly), then it does not fall within the definition of "financial interest" under this Policy and does not need to be declared under this Policy (there may be other requirements to disclose this to ICES).

13. I have been asked to give talks or presentations that are related to my clinical and/or research work and the activity is sponsored by a third party (e.g., Private Company). Would this be considered an actual or potential conflict of interest by ICES?

There are several factors that ICES considers in determining whether these talks or presentations sponsored by a third party represent an actual, potential or perceived COI.

First, ICES scientists should have full academic control over the content of their talks/presentations (i.e., they create the content and do not use slides provided by a third party, the sponsor/third party does not have the authority to approve your presentation or require changes, and you approve the final version of the talk before presentation). Ideally the letter of invitation or contract will make this explicit. Second,



ICES will consider the total number of talks/presentations sponsored by a third party and the related total honoraria in judging whether there is a COI. Third, there should be a written contract or written agreement signed for talks/presentations and ICES requires you to include the agreement/contract with your COI declaration. Formal membership in a speaker's bureau where you do not exercise academic control of talks is considered a COI. Even if these conditions about talks/presentations are met it may still be a COI if these particular features are not transparent to ICES or the audience and/or if ICES determines it otherwise compromises or could compromise the public's trust in ICES. If in doubt, ICES scientists can ask before committing to the talk/presentation if it might be considered by ICES as a COI.

14. I am a Site Investigator for a clinical trial. Do I declare it?

If this is an industry-initiated clinical trial and you are serving as the site investigator you need to declare it. If this clinical trial is being conducted at your hospital, you do not need to submit the written agreement/contract as long as your hospital is a signatory, administers the funds, and the agreement is consistent with the principles set out by the <u>Council of Academic Hospitals of Ontario (CAHO)</u>. Most teaching hospitals follow the CAHO principles if they are a signatory to the agreement/contract.

If this is investigator-initiated clinical trial, and you are the Site Investigator and it is funded by industry funding, you need to declare it. An exception would be if there was also peer-reviewed funding (e.g., CIHR, NSERC). As above if the clinical trial is being conducted at your hospital, you do not need to submit the written agreement/contract as long as your hospital is a signatory, administers the funds, and the agreement is consistent with the principles set out by the Council of Academic Hospitals of Ontario.

15. Industry has provided me with an unrestricted research grant. Do I declare it?

Yes, and it is advisable you consult with the ICES CEO before accepting unrestricted research grants. Unrestricted research grants are sometimes provided to investigators by industry as a way to provide financial support for research in particular areas that are not study specific; the funds can be used by the investigator to generally support their research or their research program.

For this to be acceptable, a number of conditions must be met:

- The funds must be administered by an institution (e.g., your hospital) and there must be a written contract/agreement with your institution as a signatory, that explicitly sets out that you have complete control over all aspects of the research, including topic, methodology, analysis and dissemination.
- You must not have other obligations to the industry that provides this unrestricted research grant, such as being on their Speakers Bureau, or as a consultant to them. A Speakers Bureau is a system used by for-profit entities which involves hiring, training, and rewarding/paying speakers to deliver academic presentations to clinical or other decision-makers to persuade the audience to use or prescribe their product. Presentations are based on materials prepared for them by the for-profit entity, and even if speakers can revise the presentation, the final control of the content rests with the for-profit entity.
- ICES will review the agreement to ensure it is independent to ICES, and, among other things, does not involve ICES data, name, logo or business tools. ICES will need to review the nature of the work to satisfy itself the service provided is not in conflict with your research and does not compromise (or be perceived to compromise or have the potential to compromise) ICES reputation and mission.



16. I have been approached to participate in a DAS Private Sector-Funded Third Party Research Project. Can I agree to this in any capacity as an ICES Scientist?

All requests for ICES Scientist participation in private sector-funded Third Party Research projects require pre-approval by the ICES CSO or CEO. ICES Core and Adjunct Scientists may participate in such studies only on a very limited basis and only when specific conditions are met. For example, Scientists may serve as consultants to such studies to provide methodologic or clinical content expertise. But they may not lead or otherwise serve in a leadership role on a project, and they may not author publications that arise from the project. Discussion with the ICES CSO or CEO in advance is strongly encouraged.



Appendix C Frequently Asked Questions – STAFF

The purpose of the FAQ is to provide examples and guidance on what constitutes a Conflict of Interest.

1. An ICES scientist asks you to work on their ICES project during non-business hours. The scientist requests that you sign a consulting agreement with their home institution (e.g., ABC Hospital).

This represents a conflict of interest. Employees are not permitted to work on ICES projects for pay outside of the employment agreement between ICES and the employee.

2. Any research group, researcher, or entity, knowing the expertise you have in analysing health administrative data, approaches you to analyse data that was obtained from ICES under the cd-link or DAS program.

This represents a conflict of interest. Employees are not permitted to work for hire on any data produced by ICES regardless of the affiliation of the principal investigator.

3. Any non-ICES research group, researcher or entity has obtained a 'cut' of OHIP and NACRS directly from the Ministry of Health and CIHI (not via ICES) respectively. Knowing your expertise in analysing health administrative data, they wish to contract you to analyse the data.

This does not represent a conflict of interest. Although the data are similar to those held at ICES, these data are not ICES data. The employee may enter into a consulting agreement with the scientist provided:

- a) The employee performs the consulting duties outside of business hours
- b) The employee does not use any ICES resources (e.g., computers, email) or intellectual property (e.g., macros, intranet resources, etc.) in the conduct of the consulting work.
- c) If publishing, the employee does not use their ICES affiliation. The employee must identify an alternate affiliation.
- 4. An employee is given the opportunity to consult with a pharmaceutical firm on projects unrelated to ICES work. The employee engages with the firm, and does not use his/her ICES affiliation, nor uses ICES resources in the conduct of this work.

This may be a conflict or may be a potential or perceived conflict of interest. Prior to any engagement with a for-profit entity, the employee should speak with their manager or director to have the engagement evaluated by the ICES COI committee. Note: there will not be any punitive action for an employee identifying a conflict of interest (actual, potential, or perceived) before engaging in the opportunity. The potential conflict will be evaluated to determine if a mitigation strategy is warranted. It is, however, contrary to Policy to accept these types of agreements without identifying these as potential conflicts of interest.

5. An employee's family member is employed by a pharmaceutical firm that manufactures a number of common drugs.



This may be a conflict or may be a potential or perceived conflict of interest. The employee should declare this relationship so that it can be evaluated by the ICES COI committee. A mitigation plan may include a requirement that the employee not participate in ICES research involving drugs manufactured by this pharmaceutical firm.

6. An employee directly holds stock or stock options (i.e., not as part of a mutual fund) in a number of companies, some that are biomedical in nature (e.g., device company, pharmaceutical company) and some that are not (start-up data management company). The employee is unsure if these would be considered to relate to their ICES research or to the work of ICES. Does the employee have to report them?

If you or your Family member receive money from investment vehicles, such as mutual funds or retirement accounts, this is not considered a conflict of interest as long as you do not directly control the investment decisions made in these investment vehicles. In these cases, you do not have to declare them. An example would be if you have a RRSP and have an investment adviser who manages your portfolio and you do not directly manage what stocks/options are purchased. If you agree to various types of investments based on your risk tolerance profile, this does not mean you directly control the investment decisions.

Otherwise, yes you should declare these stocks and stock options as you have an individual financial benefit and ICES will need to consider, for the individual case, if it could directly affect (or reasonably be perceived to affect) your research program, an ICES action, or core ICES business, mission, or reputation.