



**SPOR Evidence Alliance**

Strategy for Patient-Oriented Research

**Alliance pour des données probantes de la SRAP**

Stratégie de recherche axée sur le patient

Strategy for Patient-Oriented Research

**SPOR**

*Putting Patients First*



# Conflicts of Interest Disclosure Policy

**SPOR Evidence Alliance**

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## 1. Background

The SPOR Evidence Alliance is a partnership between researchers, research trainees, patients, caregivers, members of the public, healthcare providers, and health system decision-makers from across Canada who are committed to contributing to a learning health system by facilitating the use of reliable and high-quality scientific evidence in the decision-making process.

With a wide network of health researchers and expertise, the SPOR Evidence Alliance accepts research service requests from health system decision-makers, including patients and members of the public, and provides timely evidence-informed responses to their questions.

To minimize the influence of **conflicts of interest (COI)** within our initiative and all research activities, it is crucial that the SPOR Evidence Alliance upholds standards that are rigorous and transparent with regards to the scientific approaches used, and the reporting and sharing of research findings.

We consulted the following institutional policies and experts in preparing this document:

- Canadian Network for Observational Drug Effect Studies (CNODES): Policy on Disclosure of Personal, Occupational, Professional, and Financial Interests Related to CNODES Research<sup>1</sup>
- Canadian Agency for Drugs and Technologies in Health (CADTH): Conflict of Interest<sup>2</sup>
- Canadian Institutes of Health Research (CIHR) Ethics Guidance for Developing Partnerships with Patients and Researchers: Conflicts of Interest and Commitments<sup>3</sup>
- Canadian Medical Association Relationship with Industry Guidelines<sup>4</sup>
- St. Michael's Hospital collaborators Dr. David Mazer, Associate Scientist, and Mr. Dalton Charters, Senior Director of Research Operations

## 2. Applicability

This policy document applies to all members of the SPOR Evidence Alliance.

An **annual declaration** is mandatory for all query research teams and members of the governance structure. All other members are encouraged to complete an annual declaration, but not required until they become actively involved in a research project, governance or any working groups.

<sup>1</sup> [Canadian Network for Observational Drug Effect Studies: Policies and Procedures](#).

<sup>2</sup> [Canada's Drug Agency: Conflict of Interest](#).

<sup>3</sup> [Canadian Institutes of Health Research: Ethics Guidance for Developing Partnerships with Patients and Researchers](#).

<sup>4</sup> [Canadian Medical Association: Guidelines for physicians in interactions with industry \(PDF, 211 KB\)](#).



**Ad-hoc COI declarations** can be made upon any changes to COI status, especially at the onset and during a research project engagement. It is the responsibility of the member to update their COI disclosure when a change becomes effective.

### 3. Purpose of this Policy

The purpose of this policy is to outline the procedures in place to identify and manage any *real, perceived or potential* COIs. This policy describes the different types of COI disclosures, the protocol for reporting and managing significant COIs, and includes the COI disclosure form.

### 4. Scope of COI

A COI occurs when personal, occupational, professional, intellectual or financial interests, either directly or indirectly, affect or appear to affect the objectivity of a member's participation in the SPOR Evidence Alliance. A COI can be *real, potential, or perceived* in nature (Box 1).

#### Box 1. Nature of Conflicts<sup>2</sup>

A **real COI** arises when a member has a bias, or a personal, occupational, professional or financial relationship(s) or interests that may affect or compromise, or appear to affect or compromise their work with the SPOR Evidence Alliance.

A **potential COI** arises when a member does not currently have a real COI but can foresee that their private, personal, or professional relationship(s) or interests may have the potential to influence their work with the SPOR Evidence Alliance in the future.

A **perceived (or apparent) COI** may exist when a well-informed person believes that a SPOR Evidence Alliance member has a real or potential COI even though there may or not be a real or a potential conflict.



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**The following list illustrates some common (not exhaustive) examples of COI:**

### **Financial**

- Previous, current or potential grants and research funding
- Payments/Gifts/Gratuities/Honoraria
- Investments in business, securities or stocks
- Payments as an advisor, consultant, guest speaker, teaching webinars/seminars or chairmanship
- Travel/meeting/conference expense sponsorship
- Personal education funding

### **Intellectual**

- Public statements
- Publications and presentations
- Testimonials

### **Personal**

- Affiliations, membership or association with specific groups or organizations
- Access to confidential information
- Lobbying activities
- Advocacy, volunteering and consulting activities
- Pending contract negotiations
- Kinships, friendships, or relationships
- Financial opportunities

### **How to determine COI**

*COI can be determined using the reflective questions provided by CIHR's [Ethics Guidance for Developing Partnerships with Patients and Researchers](#).*

Questions for all SPOR Evidence Alliance members to consider:

- *Do I have personal, business, or other relationships that could conflict [or be perceived to conflict] with my role in the research, and prevent me from acting in its best interests? Have I disclosed these relationships to others involved in the research and, where appropriate, to others in my patient group or community? How can I rearrange my involvement in the research to avoid such conflicts?*
- *Does the research team, institution, funding organization, or my community have policies and processes to help me identify and manage actual and potential conflicts?*



For SPOR Evidence Alliance researchers, institutions, and funders:

- *Do we have fair and transparent policies and processes to manage and minimize conflicts of interest and commitments? Do these policies recognize that patients are multi-dimensional and wear many “hats” (as research team members, community advisors, priority setters, etc.) and bring other interests, skills, and affiliations to their role(s)?*
- *If we are considering friends, neighbours, and family members as “patient representatives”, will they be independent? Will their personal relationships present a conflict of interest that cannot be managed effectively or inhibit their participation in research?*
- *Have we consulted with our patient partners on how their commitments and interests are likely to be viewed by other patient partners in the research?*

For active physicians seeing patients, please consult the [Canadian Medical Association guidelines \(PDF, 211 KB\)](#).

## 5. Disclosure of COI

SPOR Evidence Alliance members may be required to complete any of the COI declarations listed below based on their activity within the network:

### Annual Declarations

- An **annual declaration** is mandatory for all query research teams and members of the governance structure. All other members are encouraged to complete an annual declaration, but not required until they become actively involved in a research project, governance or any working groups.
- The annual declaration should be as comprehensive as possible and should provide peers with the opportunity to discuss and mitigate any potential COI prior to engaging in an activity.
- New members are encouraged to **submit an online SPOR Evidence Alliance COI disclosure form** as part of their membership registration.

### Ad-Hoc Declarations

- **Ad-hoc declarations** can be made upon becoming aware of any changes to COI status, especially at the onset and during a research project engagement. This is particularly crucial for those projects with the potential for financial COI implications (e.g., research on a drug, technology or device available commercially). Without the completion of this form and acceptance of the management plan for the COI, in these cases, the team member may not be able to participate in the project.



- It is the responsibility of the member to update their COI disclosure when a change becomes effective. Failure to comply may affect future opportunities to collaborate and/or funding.

## 6. COI Management Plan

All COI forms are completed using the downloadable [COI disclosure form \(DOC, 91 KB\)](#) and submitted to the project lead for review and record-keeping.

### General and Project-Specific COI Management

- Upon identification of a significant COI, the Nominated Principal Investigator and the Executive Committee will provide the SPOR Evidence Alliance member with an opportunity to resolve the conflict within a reasonable time of 1-2 weeks.
- If the Nominated Principal Investigator and the Executive committee determine that a significant COI persists, **without a satisfactory mutually agreed upon management plan, the individual in question might be unable to continue participating in specific activities for the SPOR Evidence Alliance**. This will be examined on a case-by-case basis. The Nominated Principal Investigator and the Executive committee can launch an investigation of a member who is suspected of either withholding information regarding a significant COI or is failing to comply with the COI management plan. Depending on the nature and severity of the violation the Nominated Principal Investigator may choose to apply the following sanctions on the member:
  - i. Prohibiting future participation in a particular SPOR Evidence Alliance activity or committee.
  - ii. Prohibiting future participation in the SPOR Evidence Alliance.
- A member may choose to appeal the decision of the Nominated Principal Investigator and the Executive committee. This will involve providing a rationale for the continued participation of the member in the SPOR Evidence Alliance activity in question. Based on this, the Nominated Principal Investigator and Executive committee may reconsider their decision.
- In cases where the Nominated Principal Investigator or member(s) of the Executive committee have a COI, they will be recused from the decision-making process and other individuals will be appointed from the Executive committee.
- The Central Coordinating Office of the SPOR Evidence Alliance will maintain all COI documentation for up to 7 years.



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## 7. Policy Approval and Review

This COI Disclosure Policy was approved by the SPOR Evidence Alliance Nominated Principal Investigator and the Executive committee on **April 28<sup>th</sup>, 2023**.