



# Conflict of Interest Disclosure Policy

**SPOR Evidence Alliance**

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**To Be Reviewed: September 1, 2020**

**Prepared By:**

The Alliance Central Coordinating Office and Principal Investigators

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## Acknowledgements

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SPOR Evidence Alliance Executive Committee

## 1. Background

The SPOR Evidence Alliance (hereafter, the Alliance) is a partnership between researchers, trainees, patients, healthcare providers, and policy makers from across Canada who are committed to contributing to a rapid learning health system. The mission of the Alliance is to support the use of reliable and high-quality evidence in the decision-making process.

With a wide network of researchers and expertise, the Alliance accepts research requests from decision-makers, and provides timely responses to their priorities in evidence synthesis, clinical practice guidelines, and knowledge translation.

To minimize the influence of conflicts of interest (COI), it is crucial that the Alliance upholds standards that are rigorous and transparent with regard to the scientific approaches used (including scoping and developing research questions, developing and registering research protocols) and the reporting of study findings.

We consulted the following institutional policies 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>
- CADTH: Conflict of Interest <sup>2</sup>
- Systematic Prospective Assessment of Rapid Knowledge Synthesis (SPARKS) Conflicts of Interest Form

## 2. Applicability

This policy applies to all Alliance members, and membership to the Alliance is considered incomplete until the COI Disclosure Form is submitted.

## 3. Purpose of this Policy

The purpose of this policy is to outline the processes in place to identify and manage any *real, perceived or potential* COIs. This policy outlines the different types of declarations, the protocol for reporting and managing significant COIs, and includes the disclosure form to be completed by all Alliance members.

## 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 an Alliance member. 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 Alliance or with the specific project.

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

<sup>1</sup> <https://www.cnodes.ca/about/policies-procedures/>

<sup>2</sup> <https://www.cadth.ca/about-cadth/how-are-we-doing/conflict-interest>

to influence their work with the Alliance (or with a specific project) in the future.

A ***perceived (or apparent) COI*** may exist when a reasonable, well-informed person believes that an Alliance member has a real or potential COI even though there is neither a real nor a potential conflict.

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

#### 4.1 Financial

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

#### 4.2 Intellectual

- Public statements
- Publications and presentations
- Expert testimonies in court

#### 4.3 Personal

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

### 5. Disclosure of COI

Alliance members are required to complete the following types of COI disclosures based on their activity within the network:

#### 5.1 Annual Declarations

- All members who are a part of the Alliance are required to complete an annual declaration separate from project-specific declarations. The annual declaration should be as comprehensive as possible and will provide members with the opportunity to discuss and mitigate any potential COI prior to engaging in an activity. All new members must submit the Alliance COI Disclosure form upon becoming a member.

#### 5.2 Project-Specific Declarations

- All investigators and research team members involved in an Alliance project will be required to declare project-specific COI using the Alliance COI disclosure form prior to participating in the project.

#### 5.3 Ad Hoc Declarations

- Members are also required to provide updated declarations immediately in the event that their COI changes during the course of their participation in Alliance projects and/or activities

## 6. COI Management Plan

All COI forms should be submitted using the [online COI Disclosure Form](#). If you are completing a project-specific COI, the forms must also be submitted to project leads for review and record keeping.

### 6.1 General COI Management

- Upon identification of a significant COI, the Nominated Principal Investigator and the Executive Committee will provide the Alliance member with an opportunity to resolve the conflict.
- If the Nominated Principal Investigator and the Executive committee determine that a significant COI exists that cannot be resolved, they will determine whether the individual should be allowed to remain a member of the Alliance. If the Nominated Principal Investigator and Executive committee decide to allow the member to remain in the Alliance, a comprehensive plan for managing the member's COI should be developed by the Nominated Principal investigator and the Executive committee. A COI management plan might involve restricting the member's participation in the Alliance to specific tasks only.
- If the Nominated Principal Investigator and the Executive committee determine that a member's COI cannot be mitigated through a management plan, the member will be asked to withdraw their participation from either the Alliance, specific activity in question or both.
- It is the member's responsibility to follow up on the COI management plan which will involve:
  - i. A signed agreement between the member and Nominated Principal Investigator indicating the member's acceptance of the proposed plan.
  - ii. The member will provide routine updates to the Nominated Principal Investigator and the Executive committee indicating their compliance with the management plan. The Central Coordinating Office will maintain all records for up to 7 years.
  - iii. The Nominated Principal Investigator or the Executive committee can initiate periodic audits to ensure the member's compliance with the COI management plan.
- The Nominated Principal Investigator and the Executive committee can launch an investigation against 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 Alliance activity or committee.
  - ii. Prohibiting future participation in the 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 their continued participation in the Alliance activity in question based on which the Nominated Principal Investigator might reconsider their decision.

### 6.2 Project-Specific COI Management

Managing a project-specific COI follows the same steps outlined in section 1.6. Some additional considerations include:

- If a significant COI exists that cannot be resolved, the Nominated Principal Investigator and Executive committee will determine if the Alliance member should be allowed to remain on the project. If the member is allowed to remain on the project a comprehensive plan for

managing the researcher's COI should be developed. A project-specific COI management plan might involve:

- i. Restricting the member's participation in the project to specific phases only.
- ii. Restricting the member's authorship to co-authorship or acknowledgement following the ICMJE criteria.
- If the Nominated Principal Investigator and the Executive committee determine that a member's COI cannot be mitigated through a management plan, they will be asked to withdraw their participation from the Alliance project in question. The member with the COI can ask the Nominated Principal Investigator and the Executive committee to reconsider this decision.
- The Nominated Principal Investigator can launch an investigation against a member who is suspected of either withholding information regarding a significant COI or failing to comply with the COI management plan. Depending on the nature and severity of the violation, the Executive Committee may choose to apply the following sanctions on the member:
  - i. Prohibiting future participation in all Alliance activities.
  - ii. Notifying project leads if a review team member fails to follow the COI management plan.
  - iii. Notifying relevant publishers if work is published without appropriate declarations.

## 7. Policy Approval and Review

This COI policy was approved by the Alliance Nominated Principal Investigator and the Executive Committee on **October 1, 2019**. The policy will be reviewed, updated and approved annually.

# COI Disclosure Form



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## 8. Contact Information

Prefix:	First Name:	Last Name:
Email:	Confirm Email:	
Primary Institutional Affiliation:		
Your role/position:		

## 9. COI Declaration

### 9.1 Please indicate the type of COI declaration you are making:

- Annual Declaration
- Project Specific Declaration, ***please provide the project title:*** Enter Project Title.
- Ad Hoc Declaration

I have read and understand the SPOR Evidence Alliance COI Disclosure Policy and understand that I am obliged to declare all real, potential or perceived conflict(s) of interest as outlined in the policy to the SPOR Evidence Alliance Central Coordinating Office. I have reviewed the current and past activities (within the last 5 years) of myself, my spouse and immediate family for potential conflict(s) of interest that would compromise my work with the SPOR Evidence Alliance.

### 9.2 Please indicate your conflict(s) of interest status:

- I have no conflict(s) of interest to declare (please continue to section 9.4)
- I have conflict(s) of interest to declare (please continue to section 9.3)

### 9.3 I would like to highlight the following activities and interests:

Type of COI	Activities and Interests	Year	Details	Financial Value/Benefit (if applicable)*			
				\$0 - \$5000	\$5001-\$10,000	\$10,001- \$50,000	Above \$50,000
Financial	<ul style="list-style-type: none"><li>• Previous, current or potential grants and research funding</li><li>• Payments/Gifts/Gratuities/Honoraria</li><li>• Investments in business, securities</li></ul>	Click to enter Year.	Click to enter details.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

# COI Disclosure Form



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	or stocks <ul style="list-style-type: none"><li>• Payments as an advisor, consultant, speaker, educational lecturer or chair</li><li>• Travel/meeting/conference expense sponsorship</li><li>• Personal education funding</li><li>• Other</li></ul>						
Intellectual	<ul style="list-style-type: none"><li>• Public statements</li><li>• Publications and presentations</li><li>• Expert testimonies in court</li><li>• Other</li></ul>	Click to enter Year.	Click to enter details.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Personal	<ul style="list-style-type: none"><li>• Affiliations, membership or association with specific groups or organizations</li><li>• Access to confidential information</li><li>• Lobbying activities</li><li>• Advocacy, volunteering and consulting activities</li><li>• Pending contract negotiations</li><li>• Other</li></ul>	Click to enter Year.	Click to enter details.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other	Click to specify.	Click to enter Year.	Click to enter details.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

\*Please use a check mark to indicate the appropriate amount

**9.4 I hereby certify that I have disclosed all relevant information that may place me in a real or perceived conflict of interest. Except as disclosed above, I declare that I have no conflict of interest to report, as defined in the SPOR Evidence Alliance COI Policy.**

**9.5 I agree to inform the SPOR Evidence Alliance Central Coordinating office of any change in circumstances that may create a conflict of interest, as soon as it is known to me. I also agree to inform the SPOR Evidence Alliance Central Coordinating office of any as project-specific conflict of interest prior to participating in a project.**

<b>Signature:</b>	<b>Date:</b> Click or tap to enter a date.
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