POLICY FOR DECLARATION OF AFFILIATIONS AND INTERESTS

Living Concussion Guidelines: Guideline for Concussion & Prolonged Symptoms for Adults 18 Years of Age or Older

This Ontario Ministry of Healthy funded project includes the formal evaluation of the *Guidelines for the Management of Concussion/Mild Traumatic Brain Injury & Persistent Symptoms: Third Edition* to create newly revised and updated recommendations: *Living Concussion Guidelines: Guideline for Concussion & Prolonged Symptoms for Adults 18 Years of Age or Older*. Initially, the methodology will consist of an extensive literature review of appropriate studies pertaining to diagnosing, assessing, managing, and treating concussion/mTBI and persistent symptoms. After completing an assessment of the bias and quality of the literature, the findings will be discussed in a number of online meetings to revise the current guidelines.

The proposed guideline updates will then be reviewed for input from a variety of end-users, including individuals and groups likely to benefit from and/or utilize the guidelines. Consensus group members should benefit from each other's knowledge and expertise based on their individual research and/or clinical experience.

Investigators of the study acknowledge that at each step of this process there is potential for conflict of interest (COI), which might bias the recommendations. In theory, at the literature review stage, investigators might have to review and rate their own studies. Moreover, at the guideline dissemination and end-user review stage, individuals who are highly knowledgeable and involved with concussions/mTBIs might be seen as potentially biased by the constituency and/or specialty they are affiliated with. As a result, the investigators of the study have concluded that a policy of **complete** disclosure of all **potential** COIs must be implemented to ensure the most unbiased and generalizable guidelines. Thus, end-users of the guidelines can have confidence in the integrity of the steps the research team followed while revising and updating the recommendations. This process also protects the reputations of research team members as highly regarded clinicians and researchers.

The general methods to report and deal with potential COIs will follow the recommendations of:

- The Cochrane Collaboration (May 2014): published on the Cochrane Community (beta) website at http://community.cochrane.org;
- The ADAPTE Collaboration (2009): published in "Guideline Adaptation: A Resource Toolkit", Version 2.0, available at https://docplayer.net/8760104-Guideline-adaptation.html;
- The GIN-McMaster Guideline Development Checklist (Version: June 2, 2014): published by the Guidelines International Network (GIN) and McMaster University, available at http://cebgrade.mcmaster.ca/guidecheck.html

- The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2, 2018), available at https://ethics.gc.ca/eng/tcps2-eptc2_2018_chapter7-chapitre7.html
- The U.S. Preventive Services Task Force (USPTF, 2014): available at https://www.ahrq.gov/sites/default/files/publications/files/cpsguide.pdf
- The Canadian Task Force on Preventive Health Care (CTFPHC, 2014): available at https://canadiantaskforce.ca/methods/

DEFINITIONS

- **Research Team Member:** An individual who has chosen to participate in the consensus group, involved in the research process, and any persons involved in the evaluation and review.
- **Conflict of Interest Membership:** Dr. Shawn Marshall (Principal Investigator) will be responsible for actions taken by this membership and Dr. Alexander Lithopoulos (Project Coordinator) will be the other member involved.
- **Conflicts of Interest:** We adopt the TCPS 2 definition of a "conflict of interest", which states that: A conflict of interest may arise when activities or situations place an individual or institution in a real, potential or perceived conflict between the duties or responsibilities related to research, and personal, institutional or other interests. These interests include, but are not limited to, business, commercial or financial interests pertaining to the institution and/or the individual, their family members, friends, or their former, current or prospective professional associates. (TCPS 2, 2018)

CONFLICT OF INTEREST DECLARATION PROCEDURE FOR RESEARCH TEAM MEMBERS

The determination of conflicts of interest of team members will involve the implementation of two processes:

1. All group members will review this policy and complete a Conflict of Interest Declaration Form; and
2. Review by the COI Project Coordinator and Principal Investigator of the completed Conflict of Interest Declaration Forms and determination of appropriate actions.

Process for the Disclosure of Potential Conflicts of Interest

- All participants will complete the attached Conflict of Interest Declaration Form, in which they are required to provide a full disclosure of information on intellectual, financial or other potential COIs, at two time-points:
    i. the beginning of their involvement in the project; and
    ii. just prior to dissemination of the guidelines.
- Furthermore, prior to each meeting, each team member is responsible for informing the projector coordinator of any changes in their situation, since the initial completion of

the Declaration Form, which may interfere with their abilities to discuss and/or vote on a specific topic. If a group member presents new information, the Project Coordinator will maintain a record of these changes.

- Each research team member will submit separate Declaration forms to the Project Coordinator submitted electronically by e-mail.
- Completed Declaration forms will be securely kept on file at The Ottawa Hospital Rehabilitation Center. The electronic submissions will be stored in a password-protected folder on a password-protected computer.

Process for Determining Appropriate Actions

- Authors of original research that might be included as the basis for recommendations should not be involved in data extraction from their research or participate as lead reviewer for the given component of the literature review.
- Similarly, investigators who have participated in the development of previous guidelines that will be reviewed should not be involved in the process of reviewing those particular guidelines.
- Declaration Forms will be reviewed by the COI Project Coordinator or Principal Investigator to identify potential COIs that might be perceived as biasing the results. Where necessary, the Ottawa Health Science Network Research Ethics Board (OHSN-REB) will be asked to review the potential COI.
- The COI Project Coordinator will retain the right to exclude individuals felt to have serious COIs, or to exclude them from certain aspects of process, by permitting one of the following participatory actions:
    i. The member may participate as topic lead, and may discuss and vote on the topic;
    ii. The member may only discuss and vote on the topic; or
    iii. The member may not participate as topic lead, and may not discuss or vote on the topic. Publically released recommendations will denote the member's recusal from participation and voting on this topic. (CTFPHC, 2014)
- Following the Declaration Form review meeting, the COI Project Coordinator will notify each consensus group member of the recommended action and the decision will be kept on file.
    - If a group member feels that a more restrictive action is appropriate than that decided upon by the COI Project Coordinator, he or she could withdraw from any part of the process for that topic.

CONFLICT OF INTEREST DECLARATION FORM

Living Concussion Guidelines: Guideline for Concussion & Prolonged Symptoms for Adults 18 Years of Age or Older

PERSONAL INFORMATION

Full name	
Credentials	
Primary affiliation	
Other affiliations	
Date	

CONFLICTS OF INTEREST

Please provide a full disclosure of your interests and affiliations, which may potentially influence your involvement in the guideline appraisal, development, and review process, in relation to any of the guideline topics that are under consideration.

Please answer each of the following questions by placing an "x" in the appropriate boxes. For any answered questions, please describe the nature of the interest and/or relationship, and identify the relevant commercial entity.

SECTION A: WORK UNDER CONSIDERATION

Participation in Guideline Development (or Endorsement) Related to Concussion/mTBI and Persistent Symptoms

Please indicate your involvement in the development of any guidelines related to concussion/ mTBI & persisting symptoms under review (e.g. a member of the guideline development committee) or direct participation in any processes to formally endorse any of the guidelines under review, if applicable:

Title of the guideline	Role	Description of involvement

	Appraiser or reviewer of existing guideline	Developer of new guideline	Evaluator of new guideline	Endorsing existing or new guideline	Other	
	☐	☐	☐	☐	☐	
	☐	☐	☐	☐	☐	
	☐	☐	☐	☐	☐	
	☐	☐	☐	☐	☐	
	☐	☐	☐	☐	☐	

Participation in Research Related to Concussion/mTBI and Persistent Symptoms

Please indicate your participation in research related to concussion/mTBI and persistent symptoms (e.g. as an investigator, Reviewer, Developer, Evaluator, etc.) and provide a list of citations for the relevant work below, if applicable:

Topic areas	**Relevant information**	
Diagnosis/assessment of concussion	☐	
Initial management of concussion	☐	
Sport-related concussion	☐	
General recommendations regarding diagnosis/assessment of prolonged symptoms	☐	
General recommendations regarding management of prolonged symptoms	☐	
Post-traumatic headache	☐	
Sleep-wake disturbances	☐	
Mental health disorders	☐	
Cognitive difficulties	☐	
Vestibular (balance/dizziness) & vision dysfunction	☐	
Fatigue	☐	
Return to activity/work/school considerations	☐	
Other topic areas **Please specific additional topic areas in rows below. If you run out of space, add more rows.**		
	☐	
	☐	
	☐	

List of relevant citations:
Note: please number the citations and indicate which topic areas they are associated with by including the citation number in the table above.

Employment

Please indicate your employment, within the past five years, by a guideline developer or an entity having a commercial interest in the guideline under development, if applicable:

Employer and/or guideline developer	Description

Consultancy

Please indicate if you have served as a consultant, within the past five years, for a guideline developer or an entity having a commercial interest in the guideline under development, if applicable:

Employer and/or guideline developer	Description

Ownership Interests

Please indicate your ownership interests (including stock options) in any entity having a commercial interest in the guideline under development, if applicable:

Entity	Description

Research Funding

Please indicate if you are currently receiving or have previously received research funding from an entity that has a commercial interest in the guideline under development:

Entity	Description

Honouraria

Please indicate if you have been paid honouraria or received gifts from a guideline developer or an entity having a commercial interest in the guideline under development?

Entity	Description

Other potential COIs related to guideline under development

Please indicate if you have any other potential COIs related to the guideline under development that have not been addressed above:

SECTION B: RELEVANT FINANCIAL ACTIVITIES OUTSIDE THE CONCUSSION/mTBI & PERSISTENT SYMPTOMS GUIDELINE DEVELOPMENT

Please identify whether or not you engage in relevant financial activities outside the concussion/mTBI and persistent symptoms guideline development by completing each row of the table:

Financial activities	Selection		Relevant information
	No	Yes	
Board membership	☐	☐	
Consultancy	☐	☐	

Employment	☐	☐	
Expert testimony	☐	☐	
Grants	☐	☐	
Honouraria	☐	☐	
Patents	☐	☐	
Royalties	☐	☐	
Stocks	☐	☐	
Other topic areas **Please specific additional topic areas in rows below. If you run out of space, add more rows.**			
	☐	☐	
	☐	☐	
	☐	☐	

SECTION C: OTHER POTENTIAL COIs

Please indicate if you have any other potential COIs to declare:

As a member of the research team, I affirm the following:

- I have listed all potential conflicts of interest in the work under consideration.
- I have listed all of my relevant financial activities outside the driving guideline development.
- I have declared any other actual or apparent conflicts of interest related to the subject matter of the current and future topics.

Full name	
Signature	
Date	