Appendix C

Conflicts of Interest

At the beginning of the guideline development process, members of the guideline development team and the expert consensus group were asked to declare any possible conflicts of interest.

Eleven members of the expert consensus group reported that within the last five years, they have been employed by a guideline developer or an entity having a commercial interest in the guideline.

Two members of the expert consensus group reported that within the last five years, they have served as a consultant for a guideline developer or an entity having a commercial interest in the guideline.

Three members of the expert consensus group reported that they have ownership interests (including stock options) in an entity having a commercial interest in the guideline.

Two members of the expert consensus group reported that they currently or previously received funding from an entity that has a commercial interest in the guideline.

Two members of the expert consensus group reported that have been paid honouraria or received gifts from a guideline developer or an entity having a commercial interest in the guideline.

One of the expert consensus group members stated that they are a member of the Insurance Bureau of Canada and a member of the Financial Services Commission in Ontario, both of which are working groups focusing on managing various injuries and impairments in the automobile insurance sector in Canada and Ontario, respectively.

Twenty-five members of the expert consensus group reported relevant financial activities outside the guideline of interest.

None of the conflicts of interests stated above were deemed significant to the guideline. All other members declared no research involvement, funding, honoraria or other conflicts of interest.

For more specific information regarding conflicts of interest, please contact the Ontario Neurotrauma Foundation.

POLICY FOR DECLARATION OF AFFILIATIONS AND INTERESTS

Guidelines for the Management of Concussion/Mild Traumatic Brain Injury & Persistent Symptoms: Third Edition

Updating Guidelines for Concussion/mTBI Study

This Ontario Neurotrauma Foundation funded project includes the formal evaluation of the *Guidelines for the Management of Concussion/Mild Traumatic Brain Injury & Persistent Symptoms: Second Edition* to create newly revised and updated recommendations: *Guidelines for the Management of Concussion/Mild Traumatic Brain Injury & Persistent Symptoms: Third Edition*. 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 and used as evidence for a guideline development consensus meeting to revise the current ONF 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. In addition to updating the current ONF guidelines, recently published literature, relevant discussions and recommendation updates will be used to create a new, first edition patient centered version of the guidelines. 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 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 http://www.g-i-n.net/document-store/working-groups-documents/adaptation/adapte-resource-toolkit-guideline-adaptation-2-0.pdf;
- 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, 2014), available at http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter7-chapitre7/
- The Conflict of Interest Policies of:
  - The U.S. Preventive Services Task Force (USPTF, 2014): available at http://www.uspreventiveservicestaskforce.org/Page/Name/procedure-manual---section-1
  - The Canadian Task Force on Preventive Health Care (CTFPHC, 2014): available at http://canadiantaskforce.ca/methods/procedural-manual/

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 Chantal Rockwell (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 in a real, potential or perceived conflict between the duties or responsibilities related to research, and personal,

institutional or other interests. Research team members' conflicts of interest may arise from interpersonal relationships (e.g., family or community relationships), financial partnerships, other economic interests (e.g., spin-off companies in which researchers have stakes or private contract research outside of the academic realm), academic interests or any other incentives that may compromise integrity or respect for the core principles of this Policy. Conflicts may arise from an individual's involvement in dual and multiple roles within or outside an institution. While it may not be possible to eliminate all conflicts of interest, research team members are expected to identify, minimize or otherwise manage their individual conflicts. (TCPS 2, 2014)

CONFLICT OF INTEREST DECLARATION PROCEDURE FOR RESEARCH TEAM MEMBERS

The determination of conflicts of interest of team members in this study 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 in one of two formats:
  - *Physical Form*: submitted in person, by fax; or
  - *Digital Form*: submitted electronically by e-mail.
- Completed Declaration forms will be securely kept on file at The Ottawa Hospital Rehabilitation Center depending on the format of its submission by the members:
  - In-person and faxed submissions will be stored in a locked filing cabinet located within a locked research office within the premises of The Ottawa Hospital Rehabilitation Center; and
  - 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

Guidelines for the Management of Concussion/Mild Traumatic Brain Injury & Persistent Symptoms: Third Edition

Updating Guidelines for Concussion/mTBI Study

PERSONAL INFORMATION

Name	Insert Full Name
Credentials	Insert Credentials
Primary Affiliation	Insert Primary Affiliation
Other Affiliations	Insert 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

1. **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	
	☐	☐	☐	☐	☐	
	☐	☐	☐	☐	☐	
	☐	☐	☐	☐	☐	
	☐	☐	☐	☐	☐	
	☐	☐	☐	☐	☐	

2. **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** (e.g. description of involvement)	
Diagnosis/Assessment of Concussion/mTBI	☐	
Management of Concussion/mTBI	☐	
Sports-Related Concussion/mTBI	☐	
General Recommendations Regarding Diagnosis/Assessment of Persistent Symptoms	☐	
General Recommendations Regarding Management of Persistent Symptoms	☐	
Post-Traumatic Headache	☐	
Persistent Sleep/Wake Disturbances	☐	
Persistent Mental Health Disorders	☐	
Persistent Cognitive Difficulties	☐	
Persistent Vestibular (Balance/Dizziness) & Vision Dysfunction	☐	
Persistent Fatigue	☐	
Return-To-Activity/Work/School Considerations	☐	
Other Topic Areas Please specify additional topic areas in rows below. If you run out of space, you may add additional 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.

3. **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**

4. **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

5. **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

6. **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

7. **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

8. **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 (e.g. description of involvement)
	NO	YES	
Board membership	☐	☐	
Consultancy	☐	☐	
Employment	☐	☐	
Expert testimony	☐	☐	
Grants	☐	☐	
Honoraria	☐	☐	
Patents	☐	☐	
Royalties	☐	☐	
Stocks	☐	☐	
Other Topic Areas Please specify additional topic areas in rows below. If you run out of space, you may add additional 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.

Print Name: Insert Full Name

Signature:

Date:

Please submit the signed and dated form to the Project Coordinator, Chantal Rockwell, using one of the following options:

1. **E-mail:** [redacted]
   Please use your institutional e-mail address and attach either a scanned version of the Declaration Form with your signature inserted by hand or a PDF version containing your digital signature.
2. **Fax:** [redacted]
3. **In Person:** 505 Smyth Rd, Rm 2505A, Ottawa, ON, K1H8M2

Date:

COI Principal Investigator Signature: