Appendix: Financial Conflicts of Interest Checklist 2010

(Underlined terms are defined in the Glossary)

The Financial Conflicts of Interest Checklist 2010 was designed to be completed by each investigator in the context of a specific clinical research study. As awareness of financial conflict of interest issues grows, we see the checklist being completed by other study team members, such as study coordinators, research assistants and study nurses.

This checklist contains four sections: administrative information, study information, personal financial information, and authorship information. The investigator is expected to complete the checklist prospectively as the clinical research moves through its various stages. Sections 1, 2 and 3 are first filled out at the study's initiation, updated as required, and completed when the study manuscript is submitted for publication; section 4 is also completed at this time.

SECTION 1: ADMINISTRATIVE INFORMATION

This section is completed at the study's initiation and updated as necessary.

MODULE A: ADMINISTRATIVE PROFILE

ITEM	DESCRIPTOR	RESPONSE
A.1.0	**Study**	
A.1.1	Study name	_____
A.1.2	❑ Single site or ❑ multi-site	
A.1.3	Countries in which the data will be collected	_____
A.1.4	Is this a clinical trial?	❑ Yes ❑ No
A.1.4a	If you answered yes to item A.1.4:	
	Is the study registered in a primary clinical trial registry that follows international standards developed by the World Health Organization and endorsed by the International Committee of Medical Journal Editors?	❑ Yes ❑ No ❑ Don't know
	A list of approved registries can be found at http://www.who.int/ictrp/network/primary/en/index.html	
A.1.4b	What is the primary registry name and the registration number?	_____
A.1.5	Name of the institution from which the study will be coordinated	_____
A.1.6	Is any part of the study to be conducted by a contract research organization?	❑ Yes ❑ No
A.2.0	**Investigator**	
A.2.1	Name of the overall study official	_____
A.2.2	Name of the investigator completing the checklist	_____
A.2.3	What is your role in this research study? (check all that apply)	
A.2.3a	Principal investigator for the entire study	❑ Yes ❑ No
A.2.3b	Principal investigator for a site or region	❑ Yes ❑ No
A.2.3c	Co-investigator for the study	❑ Yes ❑ No
A.2.3d	Paid consultant for the study	❑ Yes ❑ No
A.2.3e	Member of steering committee	❑ Yes ❑ No
A.2.3f	Participant recruiter	❑ Yes ❑ No
A.2.3g	Other (please specify)	_____

Date the checklist section 1 was first completed (day/month/year) _____

Date(s) the checklist section 1 was updated (day/month/year) _____

SECTION 2: STUDY INFORMATION

This section is completed at the study's initiation and updated as necessary.

MODULE B: FUNDER PROFILE

ITEM	DESCRIPTOR	RESPONSE
B.1.0	**Is this study funded?**	❑ Yes ❑ No ❑ Don't know
B.1.1	If you answered yes to item B.1.0, identify the type of funding support: ❑ Financial ❑ Equipment ❑ Test kit ❑ Drug ❑ Device ❑ Other (please specify: _____)	
B.1.2	List the funder(s)	_____
B.1.3	To which categories do/does the funder(s) belong? (check all that apply):	
B.1.3a	Industry (e.g., pharmaceutical company, test or medical device company, biotech company)	❑ Yes ❑ No
B.1.3b	Government funding agency (e.g., National Institutes of Health, Canadian Institutes of Health Research, Medical Research Council)	❑ Yes ❑ No
B.1.3c	National or regional government body (e.g., National Health Service, Ministry of Health, Department of Defense)	❑ Yes ❑ No
B.1.3d	Charitable foundation (e.g., American Heart Association, The Bill & Melinda Gates Foundation, Wellcome Trust)	❑ Yes ❑ No
B.1.3e	Other(s) (please specify: _____)	❑ Yes ❑ No

MODULE C: CONTRACT PROFILE

ITEM	DESCRIPTOR	RESPONSE
C.1.0	**Is there a contract with the funder(s)?** (If you answered no or don't know, skip to module D)	❑ Yes ❑ No ❑ Don't know
	If you answered yes to item C.1.0, does your contract:	
C.1.1	include someone signing on behalf of your institution?	❑ Yes ❑ No
C.1.2	require you to obtain additional funds for this research study from other sources?	❑ Yes ❑ No
C.1.3	contain a clause that prohibits you from disclosing certain aspects about the study without the permission of the funder?	❑ Yes ❑ No
C.1.4	specify the maximum allowable time for pre-publication review by the funder?	❑ Yes ❑ No
C.1.4a	If you answered yes to item C.1.4, what is that time?	_____ days

MODULE D: STUDY TEAM AND FUNDER RELATIONSHIP PROFILE

ITEM	DESCRIPTOR	RESPONSE			
D.1.0	**Who bears final responsibility for and/or has ultimate authority over the following areas of the study?**				
D.1.1	Conceptualizing and designing the study *†	❑ Study team	❑ Funder	❑ Shared§	❑ Don't know
D.1.2	Approving the final design†	❑ Study team	❑ Funder	❑ Shared§	❑ Don't know
D.1.3	Approving the final data analysis plan	❑ Study team	❑ Funder	❑ Shared§	❑ Don't know
D.1.4	Recruiting participants	❑ Study team	❑ Funder	❑ Shared§	❑ Don't know
D.1.5	Collecting or assembling data*†	❑ Study team	❑ Funder	❑ Shared§	❑ Don't know
D.1.6	Analyzing the data*†	❑ Study team	❑ Funder	❑ Shared§	❑ Don't know
D.1.7	Interpreting the data*†	❑ Study team	❑ Funder	❑ Shared§	❑ Don't know
D.1.8	Supervising or coordinating the study	❑ Study team	❑ Funder	❑ Shared§	❑ Don't know
D.1.9	Deciding on the dissemination plan related to study results	❑ Study team	❑ Funder	❑ Shared§	❑ Don't know
D.1.10	If the study is published, who bears final responsibility for and/or has ultimate authority over the following areas of the manuscript development?				
D.1.10a	Drafting all or parts of the manuscript(s)*†	❑ Study team	❑ Funder	❑ Shared§	❑ Don't know
D.1.10b	Revising the manuscript(s) for important intellectual content*†	❑ Study team	❑ Funder	❑ Shared§	❑ Don't know
D.1.10c	Giving final approval of the version to be published*†	❑ Study team	❑ Funder	❑ Shared§	❑ Don't know
D.1.10d	Deciding where the manuscript(s) will be submitted for publication†	❑ Study team	❑ Funder	❑ Shared§	❑ Don't know
D.1.10e	Deciding the timing of the manuscript(s) submission for publication†	❑ Study team	❑ Funder	❑ Shared§	❑ Don't know
D.1.10f	Deciding authorship	❑ Study team	❑ Funder	❑ Shared§	❑ Don't know
D.1.10g	Deciding authorship order‡	❑ Study team	❑ Funder	❑ Shared§	❑ Don't know
D.1.10h	Acting as the study guarantor‡	❑ Study team	❑ Funder	❑ Shared§	❑ Don't know
D.1.10i	Providing administrative, technical or logistic support	❑ Study team	❑ Funder	❑ Shared§	❑ Don't know

* Based on International Committee of Medical Journal Editors (ICMJE), II.A.1. Byline authors, *Uniform requirements for manuscripts submitted to biomedical journals: writing and editing for biomedical publication* (2008).[1] This document describes the ICMJE's three criteria for authorship.

† Based on ICMJE, II.D.2. Potential conflicts of interest related to project support, *Uniform requirements for manuscripts submitted to biomedical journals: writing and editing for biomedical publication* (2008).[1]

‡ Based on World Association of Medical Editors (WAME), Policy statements: authorship.[2]

§ Responsibility and/or authority are shared by the study team and the funder.

Date the checklist section 2 was first completed (day/month/year) _____

Date(s) the checklist section 2 was updated (day/month/year) _____

SECTION 3: PERSONAL FINANCIAL INFORMATION

This section is completed at the study's initiation and updated as necessary.

MODULE E: FINANCIAL PROFILE

ITEM	DESCRIPTOR	RESPONSE
E.1.0	**Does this study provide you with salary support?**	❑ Yes ❑ No
E.1.1	If you answered yes to item E.1.0, what percentage of your annual salary do you estimate will be obtained from the funder(s)?	_____ %
E.2.0	**Will you personally receive direct or indirect financial benefit for your role in this study?**	❑ Yes ❑ No ❑ Don't know
E.2.1	If you answered yes to item E.2.0, what is the amount?	$ _____
E.3.0	**Will your department or institution receive or has it received financial benefit (e.g., direct funding, gifts, general use or discretionary funds or any other payment above your institution's standard administrative overhead rate) from the study funder(s)? (check all that apply)**	❑ Yes, it does now ❑ Yes, it has in the past ❑ Yes, it will in the future ❑ No ❑ Don't know
E.3.1	If you answered yes to item E.3.0, please specify the financial benefit:	_____
E.4.0	**Does this study involve the commercialization of intellectual property (e.g., through patents, copyrights or royalties from such rights)?**	❑ Yes ❑ No ❑ Don't know
E.4.1	If you answered yes to item E.4.0, who receives the financial benefit from this commercialization?	_____
E.4.2	If you answered yes to item E.4.0, how is the intellectual property commercialized (e.g., through patents, copyrights or royalties from such rights)?	_____
E.5.0	**Do you have any financial interests related to competitor(s) of the funder(s) of your study?**	❑ Yes ❑ No
E.5.1	If you answered yes to item E.5.0, please specify:	_____
E.6.0	**Do you currently have or expect to have any financial interests related to the study funder(s)?**	❑ Yes ❑ No ❑ Don't know
E.6.1	If you answered yes to item E.6.0, please specify:	_____
E.7.0	**Do any of your immediate family members (spouse or spouse equivalent, dependent child) currently have or expect to have any financial interests related to the study funder(s)?**	❑ Yes ❑ No ❑ Don't know
E.7.1	If you answered yes to item E.7.0, please specify:	_____

Date the checklist section 3 was first completed (day/month/year) _____

Date(s) the checklist section 3 was updated (day/month/year) _____

SECTION 4: AUTHORSHIP INFORMATION

This section is completed when a manuscript is being submitted for publication.

MODULE F: AUTHORSHIP PROFILE

ITEM	DESCRIPTOR	RESPONSE
F.1.0	**Is there a manuscript submitted for publication?**	❑ Yes ❑ No
F.1.1	If you answered yes to item F.1.0, what is the title of the manuscript?	_____
F.2.0	**Are you an author on this manuscript?**	❑ Yes ❑ No
F.2.1	To which aspects of the study and the manuscript development did you make a substantial contribution?	
F.2.1a	Obtaining funding‡	❑ Yes ❑ No
F.2.1b	Conceptualizing and designing the study*	❑ Yes ❑ No
F.2.1c	Providing study materials and/or recruiting participants‡	❑ Yes ❑ No
F.2.1d	Collecting or assembling data*	❑ Yes ❑ No
F.2.1e	Analyzing and interpreting data*	❑ Yes ❑ No
F.2.1f	Providing statistical expertise‡	❑ Yes ❑ No
F.2.1g	Supervising or coordinating the study‡	❑ Yes ❑ No
F.2.1h	Drafting all or part of the manuscript*	❑ Yes ❑ No
F.2.1i	Revising the manuscript for important intellectual content*	❑ Yes ❑ No
F.2.1j	Giving final approval of the version to be published*	❑ Yes ❑ No
F.2.1k	Providing administrative, technical or logistic support‡	❑ Yes ❑ No
F.2.2	Are you the study guarantor?†	❑ Yes ❑ No
F.3.0	**Are you aware of the involvement of a guest or ghost author?†**	❑ Yes ❑ No

* Based on ICMJE, II.A.1. Byline authors, *Uniform requirements for manuscripts submitted to biomedical journals: writing and editing for biomedical publication* (2008).[1] This document describes the ICMJE's three criteria for authorship.

† Based on WAME, Policy statements: authorship.[2]

‡ Derived from the *JAMA* Authorship responsibility, financial disclosure, acknowledgment, and copyright transfer/publishing agreement;[3] some are also mentioned in ICMJE[1] and WAME[2]

Date the checklist section 4 was first completed (day/month/year) _____

Date(s) the checklist section 4 was updated (day/month/year) _____

GLOSSARY

Authorship

"An 'author' is generally considered to be someone who has made substantive intellectual contributions to a published study."

– *International Committee of Medical Journal Editors*[1]

Authorship order

"Many different ways of determining order of authorship exist across disciplines, research groups, and countries. Examples of authorship policies include descending order of contribution, placing the person who took the lead in writing the manuscript or doing the research first and the most experienced contributor last, and alphabetical or random order. While the significance of a particular order may be understood in a given setting, order of authorship has no generally agreed upon meaning."

– *Faculty of Medicine Harvard Medical School*[4]

Clinical trial

"Research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes"

– *World Health Organization*[5]

Clinical trial registry

"The [online] entity that houses the clinical trial register. It is responsible for ensuring the completeness and accuracy of the information the register contains, and that the registered information [can be] used to inform health care decision making."

– *World Health Organization*[5]

Contract

"A document, dated and signed by the investigator, institution and sponsor, that sets out any agreements on financial matters and delegation/distribution of responsibilities. The protocol may also serve as a contract when it contains such information and is signed."

– *Guidelines for Good Clinical Practice (GCP) for Trials on Pharmaceutical Products*[6]

Contract research organization

"A scientific organization (commercial, academic or other) to which a sponsor may transfer some of its tasks and obligations [related to a clinical trial]. Any such transfer should be defined in writing."

– *Guidelines for Good Clinical Practice (GCP) for Trials on Pharmaceutical Products*[6]

Dissemination plan

"Specific details on how information or knowledge gained from a project is distributed and shared. Project dissemination can occur through presentations, conferences, publications and web sites."

– *Human Resources and Skills Development Canada*[7]

Financial interest

Anything of monetary value, including but not limited to:

- Salary or other payments for services

[Examples include:
  - Payment for serving as a speaker or on a speaker's bureau
  - Payment for serving on an advisory board
  - Payment for enrolling patients in clinical trials
  - Payment for travel expenses for attending conferences
  - Payment for expert testimony for the funder]

- Equity interests (e.g., stocks, stock options) [Other examples include commercial business interests such as ownerships, partnerships, joint ventures])
- Intellectual property rights (e.g., patents, copyrights and royalties from such rights)

– *U.S. Public Health Service*[8]

Funder

"[Organization] providing [the financial or monetary support] for the study through contracts, grants or donations to an authorized member of either the employing and/or care [organization]"

– *The University of Sheffield*[9]

Ghost author

"Ghost authorship exists when someone has made substantial contributions to writing a manuscript and this role is not mentioned in the manuscript itself."

– *World Association of Medical Editors*[10]

Guarantor "The person who takes responsibility for the integrity of the work as a whole, from inception to published article, and publishes that information"

– *International Committee of Medical Journal Editors*[1]

Guest author "Guest authorship is the practice of inviting those whose contribution has been scientifically trivial to be coauthors, as payment for a service (e.g. referral of a patient) or as tribute (e.g., homage to a department head). The practice of guest authorship is deceptive because the 'authors' so named gather credit without being able to account for the work."

– *Rennie et al.*[11]

Overall study official "Person(s) responsible for the overall scientific leadership of the protocol, including study principal investigator"

– *ClinicalTrials.gov*[12]

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For more information about the Financial Conflicts of Interest Checklist 2010 and to download or fill out a PDF of the checklist, go to www.openmedicine.ca/fcoichecklist

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