

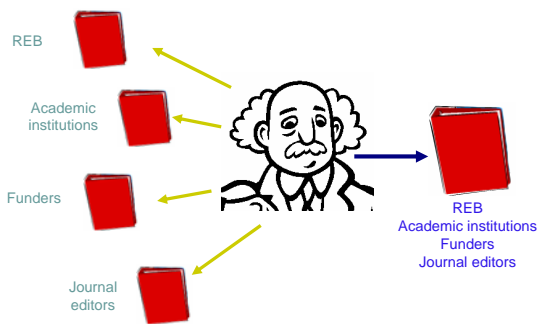
A Financial Conflicts of Interest Checklist for Clinical Research Studies

title
date

Our Goal

- To protect research participants and to maintain public trust in research, it is important that potential fCOIs are disclosed and, where indicated, steps are taken to manage its effects.

Advantages of a Single Checklist

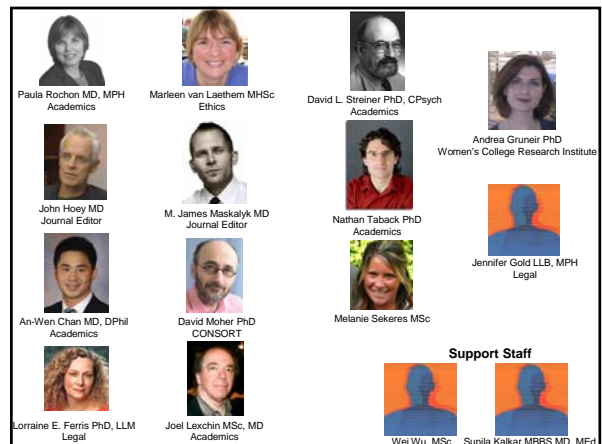


Our Checklist

- Comprehensive
- Single checklist used by multiple stakeholders
 - REB
 - Academic institutions
 - Funders
 - Journal editors
- Reports on the key aspects of research where bias can be introduced.
- Completed in a prospective manner (study inception to publication).
- Provides opportunities for early management of fCOI

The Process

- A team of 35 experts from across Canada, US and Europe
 - Research team



The Process

- A team of 35 experts from across Canada, US and Europe
 - Research team
 - External experts (n=19)
 - Research support staff (n=4)
- Combined expertise in
 - trial registration
 - research guideline development (CONSORT, EQUATOR)
 - ethics review
 - policy
 - health law
 - medical journals
 - media

The Checklist

Four sections with six modules.

- Section 1: Administrative Information section
 - Module A
 - Study information
 - Investigator information
 - Dates of checklist initiation & completion
- Section 2: Study Information section
 - Module B, C, D
 - Funder Profile
 - Contract Profile
 - Study Team & Funder Relationship
- Section 3: Personal Financial Information section
 - Module E
- Section 4: Authorship section
 - Module F

SECTION 3: PERSONAL FINANCIAL INFORMATION
This section is completed at the study's initiation and updated as necessary.

MODULE E: FINANCIAL PROFILE

ITEM	DESCRIPTION	RESPONSE
E.1.0	Does this study provide you with salary support?	<input type="checkbox"/> Yes <input type="checkbox"/> 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 funders?	_____%
E.2.0	Will you personally receive direct or indirect financial benefits for your role in this study?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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 benefits (e.g., direct funding, gifts, general use or discretionary funds or any other payment above your institution's standard administrative overhead rates) from the study funders? (check all that apply):	<input type="checkbox"/> Yes, it does now <input type="checkbox"/> Yes, it has in the past <input type="checkbox"/> Yes, it will in the future <input type="checkbox"/> No <input type="checkbox"/> Don't know
E.3.1	If you answered yes to item E.3.0, please specify the financial benefits:	_____
E.4.0	Does this study involve the commercialization of intellectual property (e.g., through patents, copyrights or royalties from such rights)?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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?	<input type="checkbox"/> Yes <input type="checkbox"/> 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)?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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)?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know
E.7.1	If you answered yes to item E.7.0, please specify:	_____

The Checklist

Advantages and Features

- Fillable form
- Skip logic allows investigators to complete only relevant sections
- Integrated glossary of terms

SECTION 1: ADMINISTRATIVE INFORMATION
This section is completed at the study's initiation and updated as necessary.

MODULE A: ADMINISTRATIVE PROFILE

ITEM	DESCRIPTION	RESPONSE
A.1.0	Study	Sample study
A.1.1	Study name	_____
A.1.2	<input checked="" type="checkbox"/> Single site or <input type="checkbox"/> multi-site	Canada
A.1.3	Countries in which the data will be collected	_____
A.1.4	Is this a clinical trial?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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? <small>A list of approved registries can be found at http://www.who.int/iaudit/</small>	Not Applicable
A.1.4b	What is the primary sponsor to which a sponsor may transfer, or its equivalent, dependent child, currently have or expect to have any financial interests related to the study funder(s)?	Not Applicable
A.1.5	Name of the institution	_____
A.1.6	Is any part of the study to be conducted by a contract research organization?	<input type="checkbox"/> Yes <input type="checkbox"/> No

Purpose & Use

- The fCOI Checklist is to be completed individually by each investigator
- The fCOI Checklist is a 'living document'
 - Modules within the checklist can be completed at different transition points over the duration of a study.
 - Modules A to E would be completed at study inception
 - Module F would be completed upon study completion



Tell us what you think – complete the
Usability Survey at:

www.openmedicine.ca/fcoichecklist



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