

Financial Conflicts of Interest Checklist 2010 for clinical research studies

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ABSTRACT

A CONFLICT OF INTEREST IS DEFINED as “a set of conditions in which professional judgment concerning a primary interest (such as a patient’s welfare or the validity of research) tends to be unduly influenced by a secondary interest (such as financial gain)” [Thompson DF. Understanding financial conflicts of interest. *N Engl J Med* 1993;329(8):573–576]. Because financial conflict of interest (fCOI) can occur at different stages of a study, and because it can be difficult for investigators to detect their own bias, particularly retrospectively, we sought to provide funders, journal editors and other stakeholders with a standardized tool that initiates detailed reporting of different aspects of fCOI when the study begins and continues that reporting throughout the study process to publication. We developed a checklist using a 3-phase process of pre-meeting item generation, a stakeholder meeting and post-meeting consolidation. External experts (n = 18), research team members (n = 12) and research staff members (n = 4) rated or reviewed items for some or all of the 7 major iterations. The resulting Financial Conflicts of Interest Checklist 2010 consists of 4 sections covering administrative, study, personal financial, and authorship information, which are divided into 6 modules and contain a total of 15 items and their related sub-items; it also includes a glossary of terms. The modules are designed to be completed by all investigators at different points over the course of the study, and updated information can be appended to the checklist when it is submitted to stakeholder groups for review. We invite comments and suggestions for improvement at www.openmedicine.ca/fcoichecklist and ask stakeholder groups to endorse the use of the checklist.

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Competing interests: Joel Lexchin was retained by a law firm representing Apotex to provide expert testimony about the effects of promotion on the sales of medications. He has also been retained as an expert witness by the Canadian federal government in its defence of a lawsuit launched challenging the ban on direct-to-consumer advertising of prescription drugs in Canada. John Hoey and James Maskalyk are associate editors and David Moher is a contributing editor at *Open Medicine*; none of them was involved in reviewing the article or deciding on its acceptance for publication. No conflicts are reported for the rest of the authors.

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A conflict of interest is defined as “a set of conditions in which professional judgment concerning a primary interest (such as a patient’s welfare or the validity of research) tends to be unduly influenced by a secondary interest (such as financial gain).”¹ Conflict of interest in biomedical research is a complex issue that has received a great deal of attention. The focus of the 2009 Institute of Medicine report on conflict of interest highlights the importance of this issue.² When there are financial interests in research studies there is concern that these relationships may influence research outcomes.³ Despite the importance of this issue, there is considerable variability in the way that these relationships have been reported.^{2,3} To protect research participants and maintain public trust in research, it is important that potential financial conflicts of interest (fCOIs) are disclosed and steps are taken, where indicated, to manage their effects.²

Investigators may not always recognize their own potential conflicts of interest and therefore would benefit from a structured method of documenting and reporting fCOI to stakeholders for assessment purposes.^{2,4} When we began this project in January 2007, various fCOI reporting disclosures were required by different stakeholder groups such as funders,⁵ academic institutions,⁶ and journal editors.⁷ These disclosures were not coordinated and were typically collected using different reporting formats (e.g., fCOI forms, fCOI statements). This meant that investigators might need to complete multiple different conflict of interest reporting disclosures for their study in order to meet the needs of different stakeholders.

We sought to provide stakeholders with a single structured checklist that contains detailed information about different aspects of fCOI. Further, we placed this information within the context of a specific clinical research study to facilitate assessment of the potential impact of the financial relationship on the research. By using a prospective format, potential conflicts can be identified at an early stage in the research process and managed where required. The checklist is initiated when the study begins and is updated throughout the study process to publication. Although we designed the checklist for clinical research studies, we recognize that other types of studies have the potential to be influenced by fCOIs.

Developing the Financial Conflicts of Interest

Checklist 2010

We developed the checklist using a 3-phase process of pre-meeting item generation, a stakeholder meeting, and

post-meeting consolidation. This process, shown in Figure 1, was adapted from one described in a recent report on developing health research reporting guidelines.⁸ Contributors to the development of this checklist are listed in the Acknowledgments.

Pre-meeting item generation. The checklist items were generated initially by our research team, whose members have expertise in research, ethics boards, law and policy, trial registration, research administration, clinical research and research guideline development—specifically the Consolidated Standards of Reporting Trials (CONSORT) and Enhancing QUALity and Transparency Of health Research (EQUATOR) Network—and were based primarily on the published literature. We identified potential items from international initiatives targeting specific aspects of fCOI. For example, items related to trial registration were derived from the World Health Organization trial registration initiative,⁹ and items related to roles in manuscripts were drawn from the International Committee of Medical Journal Editors (ICMJE) guidelines on authorship in medical publishing^{4,7} and the World Association of Medical Editors guidelines on authorship.¹⁰

After compiling an initial list of 15 items and 92 sub-items, we reviewed it using 3 groups: external experts (n = 18) with expertise in trial registration, research guideline development (CONSORT, EQUATOR), ethics review, government administration policy, health law, medical journals and media; members of the research team (n = 12); and members of our research staff (n = 4). Research staff members were included to provide a perspective from non-experts with experience in the research process.

Reviewers were asked to rate the importance of each of the items using a 5-point scale (1 = least important, 5 = most important) and to provide free-text suggestions for improving them. On the basis of these responses, we developed a second version of the checklist and, 1 month later, sent it to the participants for review. Not all of the reviewers were available for both rating sessions: 29 provided feedback to version 1, and 24 provided feedback to version 2.

Stakeholder meeting. A total of 28 people participated in a day-long stakeholder meeting in October 2007 in Toronto, Ontario, Canada. In attendance were 11 research team members and 4 research staff; 13 external experts participated using web-teleconference connections from 4 countries. We presented draft version 3 of the checklist for item discussion and identified areas for revision. The meeting was organized into 4 thematic

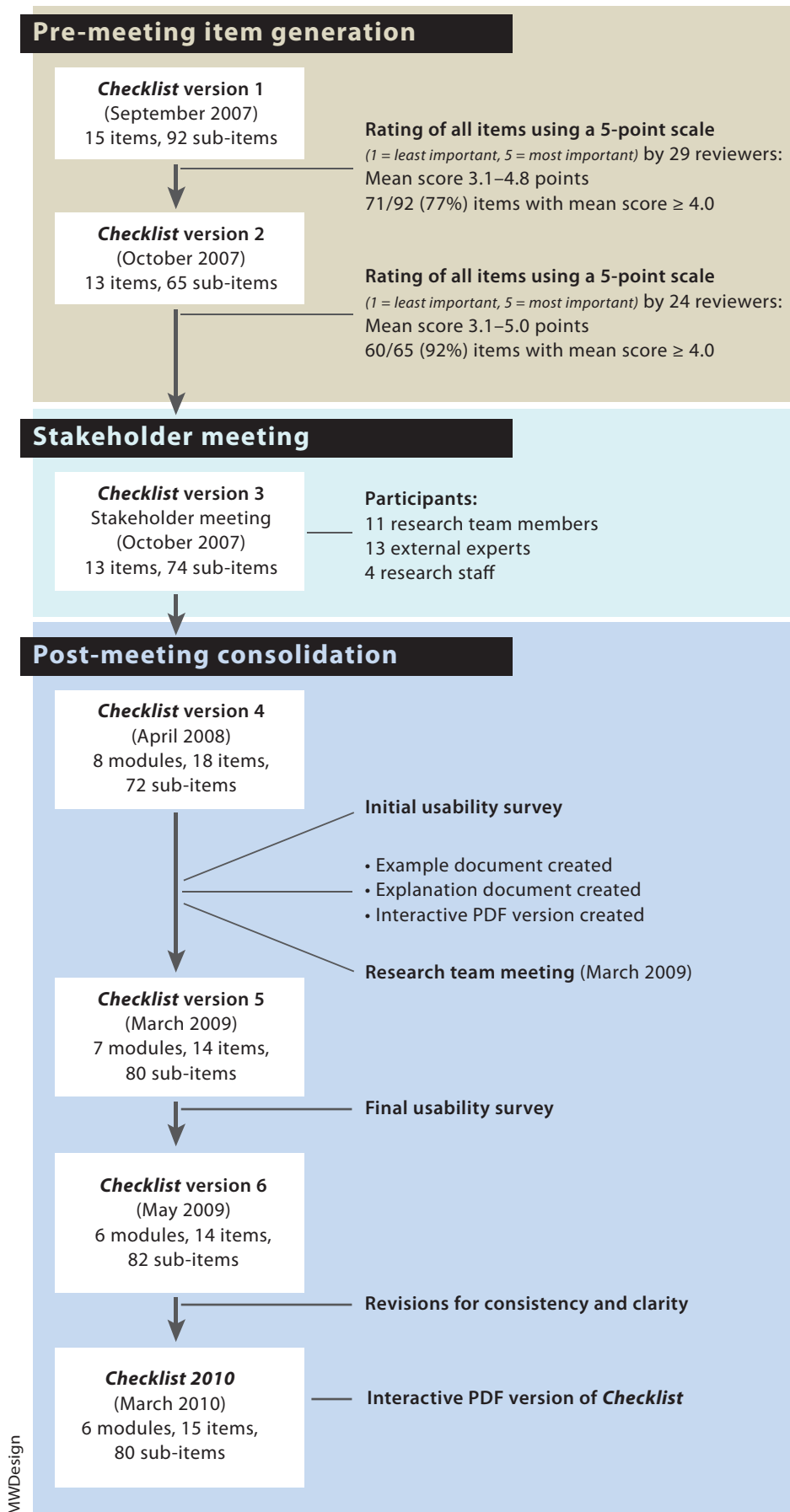


Figure 1: Financial Conflicts of Interest Checklist 2010 development process

sessions reflecting the requirements and concerns of major stakeholder groups (clinical trial registry users, journal editors, funders and policy-makers, and legal and ethics review board representatives). Each external expert participated in 1 session based on his or her area of expertise. Each session began with an overview of the checklist project, followed by a description of the particular thematic area; the session chair then led a discussion focusing on items that received discrepant ratings in the pre-meeting reviews.

Post-meeting consolidation. The post-meeting consolidation phase involved 3 steps. First, the research team incorporated the changes suggested at the stakeholder meeting into draft version 4 of the checklist—including dividing the items into modules—and then pilot-tested this version for usability with a small group of 6 investigators. We also created an example document showing examples of good reporting, an explanation document providing evidence and rationales for the items, and an interactive PDF version of the checklist.

Second, the research team met in Toronto for a 1-day consolidation meeting in March 2009 and reviewed the checklist by module and item. We reworded and reorganized items for greater clarity, decided to create a glossary to facilitate shared understanding and usage of key terms used in the items, and discussed how to improve the usability of the PDF version. We also had further discussions on how we envisioned the checklist would be implemented in practice.

In the third step of the post-meeting consolidation phase, we incorporated the most recent changes into draft version 5 of the checklist. Definitions for the glossary terms were

incorporated as roll-over pop-ups attached to the terms in the PDF. We revised the corresponding example and explanation documents and pilot-tested the checklist again for usability. After successive revisions for consistency and clarity to the draft version 6 checklist and the corresponding interactive PDF, version 7 of the Financial Conflicts of Interest Checklist 2010 was created.

Ethical review and approval of the checklist process was obtained from the Baycrest Centre and Women's College Research Institute Ethics Board, where the principal investigator was located.

The Financial Conflicts of Interest Checklist 2010

The Financial Conflicts of Interest Checklist 2010 (Table 1) consists of a 15-item form and a glossary of terms with definitions derived from sources obtained from our literature review. The checklist is also available as an interactive PDF (see the online Appendix). A feature of the PDF format is that it uses "skip logic"; it presents to investigators only selections relevant to them at the time of checklist completion based on their answers. The glossary is incorporated into the PDF through pop-ups that provide the definition when a mouse rolls over a glossary term.

The 4 sections of the checklist cover administrative information, study information, personal financial information and authorship information. These sections are divided into 6 modules containing a total of 15 items and their related sub-items. The Administrative Information section contains module A, which compiles administrative information about the study and investigator, and the date(s) when the checklist was first filled out and subsequently updated. The Study Information section contains modules B to D, which create a funder profile, contract profile, and study team and funder relationship profile respectively. The Personal Financial Information section contains module E, which creates a financial profile for each investigator of the study and author of any study publication. Finally, the Authorship Information section contains module F, which creates an authorship profile for each author involved in manuscript preparation. We have also provided an example document (Table 2), which presents examples of good reporting, and an explanation document (Box 1), which presents rationales and evidence for each of the 6 modules.

The checklist was designed as a living document that is updated as the study progresses. In general, sections 1 to 3 will be completed at study initiation and updated as necessary (for example, section 3, the Personal Financial Information section, would require updating if

the investigator's financial profile changed); section 4 will be completed when a manuscript is being prepared for publication. We anticipate that updated information would be appended to the originally completed checklist to maintain a permanent record of information related to fCOI throughout the course of the study.

We recognize that clinical research and, in particular, clinical trials are generally conducted by a team of investigators. We recommend that each investigator independently complete the entire checklist. When the checklist is submitted to a stakeholder for review, the person most knowledgeable about the study, such as the overall study official (in the case of clinical trials) or study guarantor (in the case of a manuscript submission), would collate sections of the checklist that have shared information (i.e., module A: Administrative Profile, module B: Funder Profile and module C: Contract Profile).

We pilot-tested the checklist twice during the post-meeting consolidation phase. Of the 17 participants in these usability surveys, 13 (76%) had served as an investigator in a randomized trial. Eleven (65%) respondents reported no difficulty in answering the questions. Although the checklist should be completed at different stages of the study process, for the purposes of determining usability respondents were asked to estimate the time required to complete the entire checklist: 16 (94%) required less than 20 minutes.

Discussion

We have created a checklist that aims to promote transparency at all stages of the research and publication process. An important feature of our checklist is that, as a record completed by investigators as the study evolves, it can be given to the various stakeholders who are involved at different stages of the clinical research process—funding agencies, research ethics boards, trial registries, research administrators and journal editors—which is a more consistent, efficient and effective approach than providing each group with separate, disjointed disclosures. As well, since the type of fCOI information required by stakeholders varies substantially, use of the checklist may help standardize the information.

Prospective completion of the checklist means that there is an ability to elicit fCOI disclosures throughout the study's "life stages" (e.g., from study inception to dissemination) and to maintain a public record of this information for its duration. There are 2 benefits to identifying potential fCOI situations at an early stage. First, it allows appropriate management to minimize harms; for example, the situation can be referred to a conflict

of interest committee. The Institute of Medicine report *Conflict of interest in medical research, education, and practice*² outlines steps for identifying and responding to such a committee. Second, it leads to more accurate reporting of fCOI. Investigators may be in an fCOI situation while they are conducting a study but divest themselves of it by the time they are submitting the study results for publication; such an fCOI may not be readily apparent to journal editors. The ICMJE recently published a new disclosure form for competing interests that is completed by authors at the end of a study, during the publication phase.¹¹ The form is used by journal editors, and consensus for the form's use has been built among all ICMJE journals. Given that the disclosure is occurring at the end of the research process, the opportunity to intervene and manage the fCOI is lost.

The checklist may have an educational role in that it is designed to be completed by each investigator. We recognize that clinical research is generally conducted by a team of investigators. When all investigators are asked to complete the entire checklist, irrespective of their role in the study, they will become sensitized to important issues about their study. Academic policies do not always provide investigators with clear guidance to assist them in identifying and reporting situations that may be relevant to fCOI. Further, national surveys of fCOI policies in academic settings suggest that these policies are often incomplete,^{6,12,13} fragmented¹² and difficult for investigators to understand,^{12,14} all of which limit their practical usability by investigators. Although the checklist will likely initially be completed by investigators only, it is also relevant to other study team members who may be affected by fCOI, such as study coordinators, research assistants and study nurses.

The checklist has been designed so that a completed version can be attached along with a completed CONSORT checklist in the setting of a clinical trial.¹⁵ The checklist can have an application beyond clinical research studies, and we anticipate that it will be adapted for use for other types of studies, such as basic science research. It can also be adapted for use outside of the research setting. For example, modified versions could be completed by grant review panel members making funding decisions, guideline panel members making decisions about best practices, board members making decisions about the direction of an academic organization, and by expert witnesses providing expert opinions in court proceedings or tribunals. Accordingly, we designed the checklist with sections, modules and items so that it can be tailored for use in a range of settings.

The checklist has limitations. First, our checklist was designed to focus exclusively on financial conflicts of interest. We recognize that there are non-financial conflicts of interest, but these are known to be difficult to define.¹⁶ Financial conflicts of interest are the most well recognized and the most quantifiable.¹ Second, although there are only 15 items, some users may feel daunted by the detail requested in a few of the sub-items. Our pilot testing revealed a checklist completion time of less than 20 minutes. Importantly, the entire checklist need not—and likely should not—be completed at one time. As we have recommended, different modules should be completed at different stages of the research. As users become more familiar with the checklist, and become aware of the information it compiles, the time required to complete it will likely decrease. In any case, the checklist can serve as a useful repository of essential administrative information, and the time taken to complete the checklist may be considered a worthy investment in ensuring accurate and transparent disclosure of fCOI.

Conclusion

We developed the checklist to help investigators report comprehensive structured information about fCOI to multiple stakeholder groups. We invite comments and suggestions for adaptations and improvement of the next iteration of the checklist at www.openmedicine.ca/fcoi-checklist. We also call for stakeholder groups to endorse the use of this checklist to improve transparency and mitigate fCOI in clinical research.

Contributors: Paula A Rochon conceived and designed the project, drafted the manuscript and approved it for publication. Joel Lexchin contributed to the conception and design of the checklist, participated in developing the checklist and analyzing the research, and contributed to the writing and editing of the manuscript and approved it for publication. Sunila R Kalkar and Wei Wu contributed to the conception and design of the checklist, participated in developing the checklist, performed the data analysis, and contributed to the writing of the final paper and approved it for publication. John Hoey, An-Wen Chan, Lorraine E Ferris, Melanie Sekeres, Marleen Van Laethem, M James Maskalyk, David L Streiner, Nathan Taback and David Moher contributed to the conception and design of the checklist, participated in developing the checklist and analyzing the research, and contributed to the writing of the final paper and approved it for publication. Andrea Gruneir participated in analyzing and interpreting the data and revising the manuscript for important intellectual content, and approved it for publication. Jennifer Gold was involved in the conception of the checklist, conducted some of the literature reviews, attended the January 2007 meeting, helped develop the checklist, read through the final manuscript and approved it for publication. Paula Rochon is the study guarantor.

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The following people also collaborated in the checklist item development.

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Table 1: 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	<input type="checkbox"/> Single site or <input type="checkbox"/> multi-site	_____
A.1.3	Countries in which the data will be collected	_____
A.1.4	Is this a <u>clinical trial</u> ?	<input type="checkbox"/> Yes <input type="checkbox"/> No
A.1.4a	If you answered yes to item A.1.4: Is the study registered in a primary <u>clinical trial registry</u> that follows international standards developed by the World Health Organization and endorsed by the International Committee of Medical Journal Editors? <i>A list of approved registries can be found at http://www.who.int/ictcp/network/primary/en/index.html</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know
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 <u>contract research organization</u> ?	<input type="checkbox"/> Yes <input type="checkbox"/> No
A.2.0	Investigator	
A.2.1	Name of the <u>overall study official</u>	_____
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	<input type="checkbox"/> Yes <input type="checkbox"/> No
A.2.3b	Principal investigator for a site or region	<input type="checkbox"/> Yes <input type="checkbox"/> No
A.2.3c	Co-investigator for the study	<input type="checkbox"/> Yes <input type="checkbox"/> No
A.2.3d	Paid consultant for the study	<input type="checkbox"/> Yes <input type="checkbox"/> No
A.2.3e	Member of steering committee	<input type="checkbox"/> Yes <input type="checkbox"/> No
A.2.3f	Participant recruiter	<input type="checkbox"/> Yes <input type="checkbox"/> 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?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know
B.1.1	If you answered yes to item B.1.0, identify the type of funding support: <input type="checkbox"/> Financial <input type="checkbox"/> Equipment <input type="checkbox"/> Test kit <input type="checkbox"/> Drug <input type="checkbox"/> Device <input type="checkbox"/> Other (please specify: _____)	
B.1.2	List the <u>funder(s)</u>	_____
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)	<input type="checkbox"/> Yes <input type="checkbox"/> No
B.1.3b	Government funding agency (e.g., National Institutes of Health, Canadian Institutes of Health Research, Medical Research Council)	<input type="checkbox"/> Yes <input type="checkbox"/> No
B.1.3c	National or regional government body (e.g., National Health Service, Ministry of Health, Department of Defense)	<input type="checkbox"/> Yes <input type="checkbox"/> No
B.1.3d	Charitable foundation (e.g., American Heart Association, The Bill & Melinda Gates Foundation, Wellcome Trust)	<input type="checkbox"/> Yes <input type="checkbox"/> No
B.1.3e	Other(s) (please specify: _____)	<input type="checkbox"/> Yes <input type="checkbox"/> No

MODULE C: CONTRACT PROFILE

ITEM	DESCRIPTOR	RESPONSE
C.1.0	Is there a <u>contract</u> with the funder(s)? (If you answered no or don't know, skip to module D) If you answered yes to item C.1.0, does your contract:	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know
C.1.1	include someone signing on behalf of your institution?	<input type="checkbox"/> Yes <input type="checkbox"/> No
C.1.2	require you to obtain additional funds for this research study from other sources?	<input type="checkbox"/> Yes <input type="checkbox"/> No
C.1.3	contain a clause that prohibits you from disclosing certain aspects about the study without the permission of the funder?	<input type="checkbox"/> Yes <input type="checkbox"/> No
C.1.4	specify the maximum allowable time for pre-publication review by the funder?	<input type="checkbox"/> Yes <input type="checkbox"/> 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 *†	<input type="checkbox"/> Study team	<input type="checkbox"/> Funder	<input type="checkbox"/> Shared§	<input type="checkbox"/> Don't know
D.1.2	Approving the final design†	<input type="checkbox"/> Study team	<input type="checkbox"/> Funder	<input type="checkbox"/> Shared§	<input type="checkbox"/> Don't know
D.1.3	Approving the final data analysis plan	<input type="checkbox"/> Study team	<input type="checkbox"/> Funder	<input type="checkbox"/> Shared§	<input type="checkbox"/> Don't know
D.1.4	Recruiting participants	<input type="checkbox"/> Study team	<input type="checkbox"/> Funder	<input type="checkbox"/> Shared§	<input type="checkbox"/> Don't know
D.1.5	Collecting or assembling data*†	<input type="checkbox"/> Study team	<input type="checkbox"/> Funder	<input type="checkbox"/> Shared§	<input type="checkbox"/> Don't know
D.1.6	Analyzing the data*†	<input type="checkbox"/> Study team	<input type="checkbox"/> Funder	<input type="checkbox"/> Shared§	<input type="checkbox"/> Don't know
D.1.7	Interpreting the data*†	<input type="checkbox"/> Study team	<input type="checkbox"/> Funder	<input type="checkbox"/> Shared§	<input type="checkbox"/> Don't know
D.1.8	Supervising or coordinating the study	<input type="checkbox"/> Study team	<input type="checkbox"/> Funder	<input type="checkbox"/> Shared§	<input type="checkbox"/> Don't know
D.1.9	Deciding on the <u>dissemination plan</u> related to study results	<input type="checkbox"/> Study team	<input type="checkbox"/> Funder	<input type="checkbox"/> Shared§	<input type="checkbox"/> 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)*†	<input type="checkbox"/> Study team	<input type="checkbox"/> Funder	<input type="checkbox"/> Shared§	<input type="checkbox"/> Don't know
D.1.10b	Revising the manuscript(s) for important intellectual content*†	<input type="checkbox"/> Study team	<input type="checkbox"/> Funder	<input type="checkbox"/> Shared§	<input type="checkbox"/> Don't know
D.1.10c	Giving final approval of the version to be published*†	<input type="checkbox"/> Study team	<input type="checkbox"/> Funder	<input type="checkbox"/> Shared§	<input type="checkbox"/> Don't know
D.1.10d	Deciding where the manuscript(s) will be submitted for publication†	<input type="checkbox"/> Study team	<input type="checkbox"/> Funder	<input type="checkbox"/> Shared§	<input type="checkbox"/> Don't know
D.1.10e	Deciding the timing of the manuscript(s) submission for publication†	<input type="checkbox"/> Study team	<input type="checkbox"/> Funder	<input type="checkbox"/> Shared§	<input type="checkbox"/> Don't know
D.1.10f	Deciding <u>authorship</u>	<input type="checkbox"/> Study team	<input type="checkbox"/> Funder	<input type="checkbox"/> Shared§	<input type="checkbox"/> Don't know
D.1.10g	Deciding <u>authorship order</u> ‡	<input type="checkbox"/> Study team	<input type="checkbox"/> Funder	<input type="checkbox"/> Shared§	<input type="checkbox"/> Don't know
D.1.10h	Acting as the study <u>guarantor</u> ‡	<input type="checkbox"/> Study team	<input type="checkbox"/> Funder	<input type="checkbox"/> Shared§	<input type="checkbox"/> Don't know
D.1.10i	Providing administrative, technical or logistic support	<input type="checkbox"/> Study team	<input type="checkbox"/> Funder	<input type="checkbox"/> Shared§	<input type="checkbox"/> 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?	<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 funder(s)?	_____ %
E.2.0	Will you personally receive direct or indirect financial benefit 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 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)	<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 benefit:	_____
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:	_____

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?	<input type="checkbox"/> Yes <input type="checkbox"/> 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?	<input type="checkbox"/> Yes <input type="checkbox"/> 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‡	<input type="checkbox"/> Yes <input type="checkbox"/> No
F.2.1b	Conceptualizing and designing the study*	<input type="checkbox"/> Yes <input type="checkbox"/> No
F.2.1c	Providing study materials and/or recruiting participants‡	<input type="checkbox"/> Yes <input type="checkbox"/> No
F.2.1d	Collecting or assembling data*	<input type="checkbox"/> Yes <input type="checkbox"/> No
F.2.1e	Analyzing and interpreting data*	<input type="checkbox"/> Yes <input type="checkbox"/> No
F.2.1f	Providing statistical expertise‡	<input type="checkbox"/> Yes <input type="checkbox"/> No
F.2.1g	Supervising or coordinating the study‡	<input type="checkbox"/> Yes <input type="checkbox"/> No
F.2.1h	Drafting all or part of the manuscript*	<input type="checkbox"/> Yes <input type="checkbox"/> No
F.2.1i	Revising the manuscript for important intellectual content*	<input type="checkbox"/> Yes <input type="checkbox"/> No
F.2.1j	Giving final approval of the version to be published*	<input type="checkbox"/> Yes <input type="checkbox"/> No
F.2.1k	Providing administrative, technical or logistic support‡	<input type="checkbox"/> Yes <input type="checkbox"/> No
F.2.2	Are you the study guarantor?†	<input type="checkbox"/> Yes <input type="checkbox"/> No
F.3.0	Are you aware of the involvement of a guest or ghost author?†	<input type="checkbox"/> Yes <input type="checkbox"/> 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 ICMJE¹ and WAME²

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

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

GLOSSARY

Authorship	<p>“An ‘author’ is generally considered to be someone who has made substantive intellectual contributions to a published study.”</p> <p>– <i>International Committee of Medical Journal Editors</i>¹</p>
Authorship order	<p>“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.”</p> <p>– <i>Faculty of Medicine Harvard Medical School</i>⁴</p>
Clinical trial	<p>“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”</p> <p>– <i>World Health Organization</i>⁵</p>
Clinical trial registry	<p>“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.”</p> <p>– <i>World Health Organization</i>⁵</p>
Contract	<p>“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.”</p> <p>– <i>Guidelines for Good Clinical Practice (GCP) for Trials on Pharmaceutical Products</i>⁶</p>
Contract research organization	<p>“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.”</p> <p>– <i>Guidelines for Good Clinical Practice (GCP) for Trials on Pharmaceutical Products</i>⁶</p>
Dissemination plan	<p>“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.”</p> <p>– <i>Human Resources and Skills Development Canada</i>⁷</p>
Financial interest	<p>Anything of monetary value, including but not limited to:</p> <ul style="list-style-type: none"> • Salary or other payments for services <p>[Examples include:</p> <ul style="list-style-type: none"> • 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] <ul style="list-style-type: none"> • 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) <p>– <i>U.S. Public Health Service</i>⁸</p>
Funder	<p>“[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]”</p> <p>– <i>The University of Sheffield</i>⁹</p>
Ghost author	<p>“Ghost authorship exists when someone has made substantial contributions to writing a manuscript and this role is not mentioned in the manuscript itself.”</p> <p>– <i>World Association of Medical Editors</i>¹⁰</p>

Guarantor	“The person who takes responsibility for the integrity of the work as a whole, from inception to published article, and publishes that information” – <i>International Committee of Medical Journal Editors</i> 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.” – <i>Rennie et al.</i> ¹¹
Overall study official	“Person(s) responsible for the overall scientific leadership of the protocol, including study principal investigator” – <i>ClinicalTrials.gov</i> 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

Table 2: Example document for the Financial Conflicts of Interest Checklist 2010

(Underlined terms are defined in the Glossary)

The example document is completed using a fictitious investigator and a fictitious study.

This fictitious example shows how the checklist is meant to be completed in a prospective manner by an individual investigator. Although there are excellent examples of financial conflict of interest

reporting in the medical literature, these are done in a retrospective manner and usually relate to groups of authors. The example document we provide is for illustrative purposes only and is not meant to describe preferred practice.

SECTION 1: ADMINISTRATIVE INFORMATION

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

MODULE A: ADMINISTRATIVE PROFILE

ITEM	DESCRIPTOR	EXAMPLE
A.1.0	Study	
A.1.1	Study name	Drug A versus Drug B for pneumonia in adults: multicentre randomized controlled trial
A.1.2	<input type="checkbox"/> Single site or <input checked="" type="checkbox"/> multi-site	
A.1.3	Countries in which the data will be collected	Canada and United States
A.1.4	Is this a <u>clinical trial</u> ?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
A.1.4a	If you answered yes to item A.1.4: Is the study registered in a primary <u>clinical trial registry</u> that follows international standards developed by the World Health Organization and endorsed by the International Committee of Medical Journal Editors? <i>A list of approved registries can be found at http://www.who.int/ictrp/network/primary/en/index.html</i>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know
A.1.4b	What is the primary registry name and the registration number?	ISRCTN.org and ISRCTN12345678
A.1.5	Name of the institution from which the study will be coordinated	The Fictitious Institute of Fictitious Hospital, Toronto, Canada
A.1.6	Is any part of the study to be conducted by a <u>contract research organization</u> ?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
A.2.0	Investigator	
A.2.1	Name of the <u>overall study official</u>	Dr. John Doe
A.2.2	Name of the investigator completing the checklist	Dr. Jane Doe
A.2.3	What is your role in this research study? (check all that apply)	
A.2.3a	Principal investigator for the entire study	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
A.2.3b	Principal investigator for a site or region	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
A.2.3c	Co-investigator for the study	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
A.2.3d	Paid consultant for the study	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
A.2.3e	Member of steering committee	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
A.2.3f	Participant recruiter	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
A.2.3g	Other (please specify)	
	Date the checklist section 1 was first completed (day/month/year)	18/02/2008
	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	EXAMPLE
B.1.0	Is this study funded?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know
B.1.1	If you answered yes to item B.1.0, identify the type of funding support: <input checked="" type="checkbox"/> Financial <input checked="" type="checkbox"/> Equipment <input type="checkbox"/> Test kit <input checked="" type="checkbox"/> Drug <input type="checkbox"/> Device <input type="checkbox"/> Other (please specify: _____)	The study is funded by the Fictitious Industry and the Fictitious provincial funding agency
B.1.2	List the <u>funder(s)</u>	
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)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
B.1.3b	Government funding agency (e.g., National Institutes of Health, Canadian Institutes of Health Research, Medical Research Council)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
B.1.3c	National or regional government body (e.g., National Health Service, Ministry of Health, Department of Defense)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
B.1.3d	Charitable foundation (e.g., American Heart Association, The Bill & Melinda Gates Foundation, Wellcome Trust)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
B.1.3e	Other(s) (please specify: _____)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

MODULE C: CONTRACT PROFILE

ITEM	DESCRIPTOR	EXAMPLE
C.1.0	Is there a <u>contract</u> with the funder(s)? (If you answered no or don't know, skip to module D) If you answered yes to item C.1.0, does your contract:	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know
C.1.1	include someone signing on behalf of your institution?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
C.1.2	require you to obtain additional funds for this research study from other sources?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
C.1.3	contain a clause that prohibits you from disclosing certain aspects about the study without the permission of the funder?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
C.1.4	specify the maximum allowable time for pre-publication review by the funder?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
C.1.4a	If you answered yes to item C.1.4, what is that time?	<u>30</u> days

MODULE D: STUDY TEAM AND FUNDER RELATIONSHIP PROFILE

ITEM	DESCRIPTOR	EXAMPLE			
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 *†	<input checked="" type="checkbox"/> Study team	<input type="checkbox"/> Funder	<input type="checkbox"/> Shared§	<input type="checkbox"/> Don't know
D.1.2	Approving the final design†	<input checked="" type="checkbox"/> Study team	<input type="checkbox"/> Funder	<input type="checkbox"/> Shared§	<input type="checkbox"/> Don't know
D.1.3	Approving the final data analysis plan	<input checked="" type="checkbox"/> Study team	<input type="checkbox"/> Funder	<input type="checkbox"/> Shared§	<input type="checkbox"/> Don't know
D.1.4	Recruiting participants	<input checked="" type="checkbox"/> Study team	<input type="checkbox"/> Funder	<input type="checkbox"/> Shared§	<input type="checkbox"/> Don't know
D.1.5	Collecting or assembling data*†	<input checked="" type="checkbox"/> Study team	<input type="checkbox"/> Funder	<input type="checkbox"/> Shared§	<input type="checkbox"/> Don't know
D.1.6	Analyzing the data*†	<input checked="" type="checkbox"/> Study team	<input type="checkbox"/> Funder	<input type="checkbox"/> Shared§	<input type="checkbox"/> Don't know
D.1.7	Interpreting the data*†	<input checked="" type="checkbox"/> Study team	<input type="checkbox"/> Funder	<input type="checkbox"/> Shared§	<input type="checkbox"/> Don't know
D.1.8	Supervising or coordinating the study	<input checked="" type="checkbox"/> Study team	<input type="checkbox"/> Funder	<input type="checkbox"/> Shared§	<input type="checkbox"/> Don't know
D.1.9	Deciding on the <u>dissemination plan</u> related to study results	<input checked="" type="checkbox"/> Study team	<input type="checkbox"/> Funder	<input type="checkbox"/> Shared§	<input type="checkbox"/> 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)*†	<input checked="" type="checkbox"/> Study team	<input type="checkbox"/> Funder	<input type="checkbox"/> Shared§	<input type="checkbox"/> Don't know
D.1.10b	Revising the manuscript(s) for important intellectual content*†	<input checked="" type="checkbox"/> Study team	<input type="checkbox"/> Funder	<input type="checkbox"/> Shared§	<input type="checkbox"/> Don't know
D.1.10c	Giving final approval of the version to be published*†	<input checked="" type="checkbox"/> Study team	<input type="checkbox"/> Funder	<input type="checkbox"/> Shared§	<input type="checkbox"/> Don't know
D.1.10d	Deciding where the manuscript(s) will be submitted for publication†	<input checked="" type="checkbox"/> Study team	<input type="checkbox"/> Funder	<input type="checkbox"/> Shared§	<input type="checkbox"/> Don't know
D.1.10e	Deciding the timing of the manuscript(s) submission for publication†	<input checked="" type="checkbox"/> Study team	<input type="checkbox"/> Funder	<input type="checkbox"/> Shared§	<input type="checkbox"/> Don't know
D.1.10f	Deciding <u>authorship</u>	<input checked="" type="checkbox"/> Study team	<input type="checkbox"/> Funder	<input type="checkbox"/> Shared§	<input type="checkbox"/> Don't know
D.1.10g	Deciding <u>authorship order</u> ‡	<input checked="" type="checkbox"/> Study team	<input type="checkbox"/> Funder	<input type="checkbox"/> Shared§	<input type="checkbox"/> Don't know
D.1.10h	Acting as the study <u>guarantor</u> ‡	<input checked="" type="checkbox"/> Study team	<input type="checkbox"/> Funder	<input type="checkbox"/> Shared§	<input type="checkbox"/> Don't know
D.1.10i	Providing administrative, technical or logistic support	<input checked="" type="checkbox"/> Study team	<input type="checkbox"/> Funder	<input type="checkbox"/> Shared§	<input type="checkbox"/> 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)

18/02/2008

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	EXAMPLE
E.1.0	Does this study provide you with salary support?	<input checked="" 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 funder(s)?	<u>10</u> %
E.2.0	Will you personally receive direct or indirect financial benefit for your role in this study?	<input checked="" 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?	\$ <u>5,000</u>
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)	<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 checked="" 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 benefit:	Not Applicable
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 checked="" 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?	Not Applicable
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)?	Not Applicable
E.5.0	Do you have any <u>financial interests</u> related to competitor(s) of the funder(s) of your study?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
E.5.1	If you answered yes to item E.5.0, please specify:	Not Applicable
E.6.0	Do you currently have or expect to have any financial interests related to the study funder(s)?	<input checked="" 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:	<u>I am receiving funding from Fictitious Industry to study the prevalence of pneumonia in the community</u>
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 checked="" 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:	<u>My husband is a consultant for Fictitious Industry</u>
Date the checklist section 3 was first completed (day/month/year)		<u>18/02/2008</u>
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	EXAMPLE
F.1.0	Is there a manuscript submitted for publication?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
F.1.1	If you answered yes to item F.1.0, what is the title of the manuscript?	Drug A versus Drug B for pneumonia in adults: multicentre randomized controlled trial
F.2.0	Are you an author on this manuscript?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> 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‡	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
F.2.1b	Conceptualizing and designing the study*	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
F.2.1c	Providing study materials and/or recruiting participants‡	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
F.2.1d	Collecting or assembling data*	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
F.2.1e	Analyzing and interpreting data*	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
F.2.1f	Providing statistical expertise‡	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
F.2.1g	Supervising or coordinating the study‡	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
F.2.1h	Drafting all or part of the manuscript*	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
F.2.1i	Revising the manuscript for important intellectual content*	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
F.2.1j	Giving final approval of the version to be published*	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
F.2.1k	Providing administrative, technical or logistic support‡	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
F.2.2	Are you the study guarantor?†	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
F.3.0	Are you aware of the involvement of a guest or ghost author?†	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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 ICMJE¹ and WAME²

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

10/03/2010

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

GLOSSARY

Authorship	<p>“An ‘author’ is generally considered to be someone who has made substantive intellectual contributions to a published study.”</p> <p>– <i>International Committee of Medical Journal Editors</i>¹</p>
Authorship order	<p>“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.”</p> <p>– <i>Faculty of Medicine Harvard Medical School</i>⁴</p>
Clinical trial	<p>“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”</p> <p>– <i>World Health Organization</i>⁵</p>
Clinical trial registry	<p>“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.”</p> <p>– <i>World Health Organization</i>⁵</p>
Contract	<p>“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.”</p> <p>– <i>Guidelines for Good Clinical Practice (GCP) for Trials on Pharmaceutical Products</i>⁶</p>
Contract research organization	<p>“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.”</p> <p>– <i>Guidelines for Good Clinical Practice (GCP) for Trials on Pharmaceutical Products</i>⁶</p>
Dissemination plan	<p>“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.”</p> <p>– <i>Human Resources and Skills Development Canada</i>⁷</p>
Financial interest	<p>Anything of monetary value, including but not limited to:</p> <ul style="list-style-type: none"> • Salary or other payments for services <p>[Examples include:</p> <ul style="list-style-type: none"> • 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] <ul style="list-style-type: none"> • 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) <p>– <i>U.S. Public Health Service</i>⁸</p>
Funder	<p>“[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]”</p> <p>– <i>The University of Sheffield</i>⁹</p>
Ghost author	<p>“Ghost authorship exists when someone has made substantial contributions to writing a manuscript and this role is not mentioned in the manuscript itself.”</p> <p>– <i>World Association of Medical Editors</i>¹⁰</p>

- 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

Box 1: Explanation document for the Financial Conflicts of Interest Checklist 2010

INTRODUCTION

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 (fCOI) 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

This module compiles administrative information about the study and the investigator filling out the checklist. Administrative information helps characterize the study and place it in context.

Identifying the countries involved in data collection for a specific clinical trial provides an opportunity to evaluate the standards in place for the ethical conduct of trials across sites.^{1,2}

Information about clinical trial registration is included to promote accountability and transparency of research. Trial registration helps mitigate the potential impact of fCOI by publicly documenting important protocol information before a study begins and participants are enrolled. Two decades ago Chalmers described the serious problem of underreporting of clinical trials that occurs when results are either published in insufficient detail or not published at all, and he advocated for trial registration.³ A more recent systematic review has shown that underreporting of clinical trials continues to be an issue.⁴ This has important implications for clinical practice because it means that the body of published articles may exaggerate the effectiveness of a given therapy.

The International Committee of Medical Journal Editors (ICMJE) requires registration for trials published in journals that adhere to ICMJE standards.⁵ The World Health Organization's International Clinical Trials Registry Platform was established in 2005 to create global standards for trial registration.⁶ Further, trial registration and results reporting are now required by law in the United States.⁷ Information is requested about the role that each individual completing the checklist will play in the study's conduct. This informs stakeholders about the extent to which he or she is involved in the study and provides a perspective on the level of knowledge and responsibility the investigator will have of the study. An overall study official will have a comprehensive understanding of all of the key issues related to the organization of the study. Other investigators may have more limited knowledge about certain aspects of the study.

SECTION 2: STUDY INFORMATION

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

Module B: Funder Profile

This module compiles information about all of the sources of funding for the study.

Research studies receive funding from different sources. Information in this module is requested about funders from categories including industry, government, charitable foundations and others. Financial conflicts of interest can occur with a range of different funders. Conflicts of interest related to the conditions of the funding have the potential to influence research findings.^{8,9} Industry funding is important to consider because 70% of clinical drug trial funding in the US is estimated to be from industry sources,¹⁰ and a quarter of academic investigators in biomedical research are estimated to receive industry funding for their research.¹¹ Accordingly, reporting of funding sources is relevant in assessing possible fCOI.

Module C: Contract Profile

This module addresses contracts with funders and is filled out by investigators who have received a contract for the study.

Contracts vary depending on the institution, the nature of the study, and the funder. Considerable concern has been expressed about restrictive confidentiality clauses,^{12,13,14} which can be used to delay or prevent study information from being made public and thereby interfere with the publication of negative results or unfavourable data.¹⁴

Investigators need to retain the right to decide on publication of the study results to ensure that the study results contribute to publicly available knowledge. ICMJE supports the sponsor's right to review a manuscript before it is published but suggests a defined time of 30–60 days to allow for the filing of additional patent protection.¹⁵ One academic organization suggests extending the time to 90 days, and in exceptional cases to as long as 6 months.¹²

Module D: Study Team and Funder Relationship Profile

This module explores the relationship between the study team and the funder and identifies who bears final responsibility for and authority over study conduct and manuscript development activities that are susceptible to fCOI.

An fCOI exists when a funder controls key study elements that can influence the validity and dissemination of results.¹⁶ In its Uniform Requirements for Manuscripts Submitted to Biomedical Journals, ICMJE states that “Authors should describe the role of the study sponsor, if any, in study design; collection, analysis, and interpretation of data; writing the report; and the decision to submit the report for publication.”⁸ Funders should not have sole control over the data or decisions to publish.¹⁵

In filling out the response options (study team, funder, shared, don't know), investigators describe the relationship between the study team and the funder.

SECTION 3: PERSONAL FINANCIAL INFORMATION

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

Module E: Financial Profile

This module compiles information related to the disclosure of financial relationships in order to create a financial profile. The information requested pertains to funding that the individual and his or her institution may receive.

When an investigator stands to gain financially from the research, this may bias their judgment about the study conduct and manuscript development. The influence that financial reward may have on investigators' judgment and behaviour has been the subject of much discussion. Recommendations have been made related to the reporting of financial interests by investigators.¹⁷ These are consistent with the United States Public Health Service regulations.¹⁸ Social science research suggests that any gift has the potential to create an fCOI.¹⁹ This finding is important because research-related gifts are common. In a study using a sample of researchers receiving federal funds, some 43% reported receiving research-related gifts from commercial entities.²⁰ When an institution stands to gain financially from the research conducted by its investigators, this creates the potential for institutional fCOI. Left unmanaged, institutional fCOI could misdirect research agendas. Financial conflicts of interest can also occur in relation to competitors, who have a vested interest in having their product perform better than the comparison product.

Partnerships between funders and academia can lead to institutional fCOI. Funded clinical trials generally provide academic institutions with financial compensation for administering or participating in trials. In some cases they may receive payment above the institution's standard administrative overhead charges.

Research discoveries can lead to commercialization of intellectual property and generate revenue, thereby creating potential for both investigator and institutional fCOI in the intellectual property.²¹

Although fCOI is usually thought of in the context of the investigator, it is also important to consider relationships their immediate family members may have with funders.

SECTION 4: AUTHORSHIP INFORMATION

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

Module F: Authorship Profile

This module compiles authorship information, but it should be completed by all investigators, even if they are not listed as authors, since it provides the opportunity to identify the contributions of each investigator leading to publication.

When a study is published, it is essential that readers have a clear understanding of the roles that the authors played when conducting the study and preparing the manuscript. Accurate and transparent reporting of all of the contributions to a published article establishes accountability, responsibility and appropriate credit for scientific work.²²

Module F contains items that are based on the ICMJE Uniform requirements criteria for authorship credit.⁸ The three criteria for authorship are “1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published.” These criteria have been widely accepted by organizations including WAME²² and Consolidated Standards of Reporting Trials (CONSORT).²³

Investigators can contribute to the development of a manuscript in ways that are not encompassed by the three ICMJE authorship criteria. These roles include obtaining funding, providing study materials and/or recruiting participants, providing statistical expertise, supervising or coordinating the study, and providing administrative, technical or logistic support

In its criteria for authorship, WAME discusses guest or ghost authors, stating that it is dishonest not to mention someone who wrote part of the manuscript (i.e., a ghost author) or to include investigators as authors only because of their reputation (i.e., a guest author).²² Ghost authorship needs to be acknowledged as this involvement has the potential to bias the presentation of research findings.²⁴ An item related to these practices is included in the checklist, and definitions are provided in the glossary.

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