

Disclosing Competing Interests in CDC Guidelines

1. Introduction

This document describes CDC's Office of the Associate Director for Science (OADS) requirements for disclosing the competing interests of authors and members of steering committees and workgroups who develop and report on CDC guidelines and recommendations. A competing interest exists when professional judgment or actions concerning a primary interest (such as patients' or public's welfare or the validity of research) may be improperly influenced by a secondary interest such as financial gain, professional advancement, or personal rivalry.^{1, 2} The commonly used "conflict of interest" term often refers to a narrower understanding of secondary interests such as financial gain. However, the term competing interest is used in this document to indicate a broader meaning of secondary interests, such as nonfinancial personal gain. CDC guidelines and recommendations have the potential to influence practice, policy, and the allocation of resources on a wide scale. Therefore recommendations must be based on objective assessments of the evidence, and values or preferences that influence judgment must be transparent and not prejudiced by secondary interests.³

2. Requirements for Reporting Competing Interests in CDC Guidelines

CDC's OADS requires all authors, steering committeeⁱ and workgroup membersⁱⁱ, including federal employees, interns and fellows, and external members participating in the development and reporting of a CDC guideline to disclose any competing interests. To assess competing interests, OADS recommends the use of the ***Competing Interest and Confidentiality Self-Certification for CDC Guidelines*** (see Step 1 of this document). Contract employees are also required to disclose competing interests. These employees and their employing agencies may also need to follow contract language or Procurement and Grants Office (PGO) requirements. Using the information from this form, the OADS also requires that a ***Disclosure of Competing Interest Statement for CDC Guidelines*** be placed in the document containing the CDC guidelines (see Step 2 of this document for an example of such language).

NOTE: These OADS requirements do not apply to members of federal advisory committees and their workgroups formed under the Federal Advisory Committee Act (FACA). They file their own conflict of interest forms. FACA information is available at the following websites: <http://www.cdc.gov/maso/FACM/facmhome.htm> and <http://intranet.cdc.gov/maso/cmppa/index.html>. The Management Analysis and Services Office (MASO) manages FACA processes, which are separate from this process and therefore are not subject to completing an OADS Disclosure of Competing Interest Statement. To determine whether a group is subject to FACA requirements, contact the MASO Federal Advisory Committee Policy and Oversight Team (CDC) at facmp&o@cdc.gov or (770) 488-4707.

ⁱ Steering Committee: The steering committee oversees guideline development and writing and approval of recommendations. It may include a few members of the guideline workgroup.

ⁱⁱ Workgroup: Anyone who contributes to the planning, development, scientific evidence gathering and synthesis, drafting, , and publication of CDC guidelines and recommendations

3. Guidance for Assessing and Disclosing Competing Interests

Guidance for assessing potential competing interests and developing competing interest statements are provided in steps 1 and 2 below. In step 1, all members of steering committees or workgroups complete the form ***Competing Interest and Confidentiality Self-Certification Form for CDC Guidelines***. In Step 2, the workgroup leader or designee compiles the competing interest information from these forms to develop a ***Disclosure of Competing Interest Statement for CDC Guidelines***.

Step 1. Assessing Competing Interests

OADS requires authors or members of steering committees or workgroups to complete the form ***Competing Interest and Confidentiality Self-Certification Form for CDC Guidelines (page 3)*** before participating in guideline development. If workgroups use a different form, it needs to be approved by CDC, Department of Health and Human Services (HHS), the Office of Personnel Management (OPM), or another federal authority. Disclosing competing interests does not necessarily prevent anyone from becoming a member of a guideline workgroup or otherwise participating in guideline development. In some cases, where the expertise is needed, competing interests may be unavoidable. If a competing interest exists, the individual may decline or be asked to decline participation during any period of guideline development where the competing interest may exist. However, it is ultimately up to the guideline CDC steering committee or a designated workgroup leader to decide whether and how to retain or excuse anyone with a competing interest.

If there are competing interests, possible options may include: 1) allowing the individual to participate and reporting the competing interest in the guideline document; 2) prohibiting the individual from participating in portions of the process where the competing interest is greatest; or 3) prohibiting the individual from participating entirely. In a few sentences, authors need to summarize in the methods section of the guideline document: a) what form they used to assess competing interests and b) how they managed competing interests in the workgroup.

COMPETING INTEREST AND CONFIDENTIALITY SELF-CERTIFICATION FORM FOR CDC GUIDELINESⁱⁱⁱ

Note: This is an example of a form that CDC staff can use and tailor to meet the needs of a particular guidelines and recommendation working group. This is not an official form approved by the Office of Government Ethics and does not need to be reviewed by the CDC Ethics Office, nor is it required to be filed and maintained in that office.

Steering Committee/Working Group Name: _____

Dates of Meeting: _____

Name of Participant: _____

Check only one:

- I have read this *Competing Interest and Confidentiality Self-certification for CDC Guidelines* form and have examined the group's charge and the meeting agenda. I have also read the statements below, and I hereby certify that I do not have a perceived or actual competing interest in relation to any agenda item.

- I have read this *Competing Interest and Confidentiality Self-certification CDC Guidelines* form and have examined the group's charge and the meeting agenda. I have also read the statements below, and I hereby certify that I have a perceived or actual competing interest with an item on the agenda. I will disclose the competing interest to the federal employee workgroup leader before discussion of that item so it can be reflected in one of the workgroup's meeting minutes and the *Disclosure of Competing Interest Statement for CDC Guidelines and Recommendations*, along with the determination of how the conflict was remedied.

Statements: If one or more of the following statements is true, then the individual should disclose and discuss that statement with the workgroup.

- The purpose of the guideline for which this disclosure form is prepared is a critical review and evaluation of my work outside this workgroup or that of my employer.

- I have a professional obligation that requires me to publicly defend or defeat an established position on an issue relevant to the functions to be performed in this working group activity.

- To the best of my knowledge, my participation in this working group activity will enable me to obtain access to a competitor's or potential competitor's confidential proprietary information.

ⁱⁱⁱ Guideline developers include all authors, steering committee and workgroup members, including CDC federal employees, students, and fellows participating in the development and reporting of a CDC guideline.

- As a current or former U.S. government employee (civilian or military), there are federal competing interest restrictions that may apply to my service in connection with this working group activity.
- I am interested in seeking an award under the program for which the working group is developing the request for proposals, work statement, or specifications, and I am employed in some capacity by, or have a financial interest in or other economic relationship with, any person or organization that to the best of my knowledge is interested in seeking an award under this program.
- I or a member of my immediate family hold a financial, equity, or proprietary interest in, or receive research support from, an organization whose product or product concept is involved in the deliberations of this working group.
- I or a member of my immediate family hold financial, equity, or proprietary interest in, or receive research support from, an organization whose product or product concept is competing with a product or product concept being discussed by this working group.
- I or a member of my immediate family is seeking employment in an organization or serve as an officer, director, trustee, partner, or employee of an organization whose product or product concept competes with, is involved in the deliberations of, or would benefit from research in an area that is on this working group's agenda.
- I or a member of my immediate family hold financial, equity, or proprietary interest in, or receive research support from, an organization whose product or product concept is being discussed by this working group or would substantially benefit from research emphasis in a defined area.

I fully understand the confidential nature of the discussions held during sessions of the working group and agree: (1) to destroy or return all materials related to the meetings; (2) not to disclose or discuss the materials associated with the meetings or my evaluations with anyone except with the CDC guideline steering committee to which the working group reports; and (3) to refer all inquiries concerning the meeting to the federal official managing the working group (federal official: a CDC full-time equivalent employee and is a member of the guideline workgroup). I hereby certify that the above information is true and complete to the best of my knowledge and that, as appropriate, I have disclosed and discussed any competing interest or applicable statement with the workgroup.

Signature: _____

Date: _____

(Participant's Name)

Reviewed by: _____

Date: _____

Step 2. Disclosing Competing Interests

Authors should also develop a ***Disclosure of Competing Interest Statement for CDC Guidelines*** that is placed at the end of the guideline document. The workgroup leader or designee compiles the competing interest information to develop a ***Disclosure of Competing Interest Statement for CDC Guidelines***. A disclosure of competing interest statement describes competing interests among authors, steering committee, and workgroup members that participated in the development and writing of guidelines and recommendations. This disclosure statement is inserted in the back of a CDC guideline and recommendation document after the list of steering committee and workgroup names and affiliations. The statement must be included in the guideline document before it is submitted for CDC clearance.

Examples of Disclosure of Competing Interest Statements for CDC Guidelines

The following are two examples of suggested language for a Disclosure of Completing Interest Statement. The first has no competing interests and the second includes competing interests. Examples of disclosure statements can be tailored for each CDC workgroup.

- “CDC, our steering committee, and workgroup wish to disclose that they have no financial interests or other relationships with the manufacturers of commercial products, suppliers of commercial services, or commercial supporters that would unfairly influence these CDC guidelines and recommendations.”
- “CDC, our steering committee, and workgroup wish to disclose that they have no financial interests or other relationships with the manufacturers of commercial products, suppliers of commercial services, or commercial supporters that would unfairly influence these CDC guidelines and recommendations with the following exceptions: (name) wishes to disclose that s/he is funded by (name of company); (name) has received research grants from (name of companies) while s/he served as a principal investigator of grants; (name) wishes to disclose that her/his institution receives funding from (name of agency) for her participation in a clinical trial and that her/his spouse is employed by (name of company); (name) wishes to disclose that this work was completed as part of the CDC Experience, a one-year fellowship in applied epidemiology at CDC made possible by a public/private partnership supported by a grant to the CDC Foundation from (name of company). Presentations will not include discussion of the unlabeled use of a product or a product under investigational use.”

Other Examples from Published Literature

- “CDC, our planners, and our content experts wish to disclose that they have no financial interests or other relationships with the manufacturers of commercial products, suppliers of commercial services, or commercial supporters.”⁴
- “CDC, our planners, and our content experts wish to disclose that they have no financial interests or other relationships with the manufacturers of commercial products, suppliers of commercial services, or commercial supporters. Planners have reviewed content to ensure there is no bias. This document will not include any discussion of the unlabeled use of a product or a product under investigational use, with the exception that some of the recommendations in this document might be inconsistent with package labeling. CDC does not accept commercial support.”⁵
- “Our subject matter experts wish to disclose that they have no financial interests or other relationships with the manufacture of commercial products, providers of commercial services, or commercial supporters. This report does not include any discussion of the unlabeled use of commercial products or products for investigational use.”⁶
- The authors T.M., C.A.U., R.K.A., I.L., G.K., and K.B.S. report no actual or potential conflicts of interest. C.A.U., R.K.A. and I.L. received funding from the CDC to support the guideline development process.”⁷
- “CDC, our planners, and our content experts disclose that they have no financial interests or other relationships with the manufacturers of commercial products, suppliers of commercial services, or commercial supporters. Presentations will not include any discussion of the unlabeled use of a product or a product under investigational use. CDC does not accept commercial support.”⁸
- “CDC, our planners, and our presenters wish to disclose they have no financial interests or other relationships with the manufacturers of commercial products, suppliers of commercial services, or commercial supporters with the exception of Jeffrey P. Salomone, who wishes to disclose he received an honorarium as a consultant and on the Advisory Board for Schering-Plough Pharmaceuticals and Stewart C. Wang, who received research grants from General Motors and Toyota Motors while he served as a principal investigator of Grants. Presentations will not include any discussion of the unlabeled use of a product or a product under investigational use.”⁹
- The developers of these guidelines wish to disclose that they have no financial interests or other competing interests with the manufacturers of commercial products or suppliers of commercial services related to vaccines including any related to hepatitis B vaccines, with the following exceptions: David Weber, MD, wishes to disclose that he served as a consultant and on a speakers’ bureau, whether paid or unpaid (e.g., travel related reimbursement, honoraria), for the following vaccine manufacturers: Merck, Sanofi, and Pfizer pharmaceutical companies. Amy B Middleman, MD, also wishes to disclose that she received grant funding from the following pharmaceutical companies: MedImmune, Sanofi, and Merck.”¹⁰
(Note: This statement is listed at the end of the document)

4. Acknowledgements

We wish to acknowledge the following individuals who made the development of this document possible through their time and expertise:

Sudevi Ghosh, JD, senior attorney, CDC Office of the General Counsel

Chris Cox, JD, senior attorney, HHS Office of the General Counsel

5. References

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