

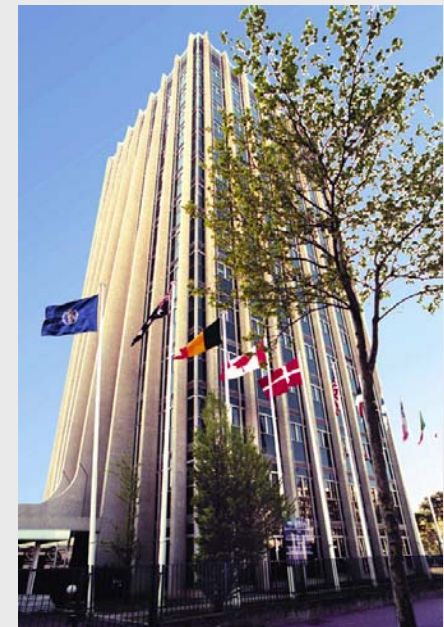


World Health Organization  
Organisation mondiale de la Santé

# Avoiding conflicts of interests in the *IARC Monographs*: lessons learned

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# Overview

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Identifying conflicting interests

Addressing conflicting interests

“Best experts” or impartial experts?

Keeping meetings free from interference





# Identifying conflicting interests: IARC uses WHO's criteria

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## Employment and consulting (past 4 years or anticipated)

- Employment by an interested party
- Consulting, especially on matters before a court or government agency
- Service as a science advisor, expert witness, meeting participant, or speaker

## Research support (past 4 years or anticipated)

- Support for the expert's own research
- Support for others in the expert's research unit or organization
- Equipment and supplies

## Financial interests (current interests)

- Stock, other securities, and business interests
- Intellectual property (for example, patent rights)



# Identifying conflicting interests: some challenges

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## Many experts do not recognize certain activities as conflicts

- Expert testimony: “I’m just telling the truth”
- Expert testimony: “I’ll get paid no matter which side wins”
- Research support: “I have the final say in what gets published”
- Research support: “Vaccines and drugs save lives”

## A few experts don’t recognize this as an issue

- “I didn’t disclose it because the money doesn’t affect my views”
- “Just get all the experts together and let them fight it out”

## Experts with conflicts sometimes get extra help from special interests

- Unseen employees have been sent to Lyon to be near our meetings
- These special interests have staff at their disposal to review the materials under consideration, answer queries, and prepare alternative text





# Identifying conflicting interests: lessons learned

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## Ask specific, objective questions

- “Have you served as an expert witness in a court case involving [xxx]?”
- “Have you prepared remarks on this topic for a government review?”

## Look for repeated activities that suggest an ongoing relationship with interested parties

## Verify the absence of conflicting interests

- Check recent papers for acknowledgments of research support
- Search the internet for links to special interests
- Follow-up with a conversation with the expert

## Ask the experts to update their declarations at the meeting

- This promotes a common understanding of what constitutes a conflict
- It also provides an opportunity to identify newly-acquired (or solicited) conflicting interests





# Identifying conflicting interests: speculative vs. objective questions

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## Speculative question (example)

If this committee activity were to provide the basis for government regulatory action, could the research funding and support for you or your close research colleagues and collaborators be directly affected?

## Objective question (example)

Please declare financial interests, employment and consulting, and research support derived from commercial entities whose operations or products result in human exposure to 1,3-butadiene, ethylene oxide, or vinyl chloride.



# Addressing conflicting interests: some different approaches

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**Ignore the issue (fewer organizations are doing this)**

**Disclosure only**

**Disclosure only, but check that not too many experts have conflicts**

**Balance experts with a conflicting interest with other experts who have no interests**

**Balance experts with a conflicting interest with other experts who have opposing interests**

**Strive to avoid conflicting interests**





# Addressing conflicting interests: Int'l C'tee of Medical Journal Editors

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**“Public trust in the peer review process and the credibility of published articles depend in part on how well conflict of interest is handled during writing, peer review, and editorial decision making.”**

**“The potential for conflict of interest can exist whether or not an individual believes that the relationship affects his or her scientific judgment.”**

**“Disclosure of these relationships is also important in connection with editorials and review articles, because it is can be more difficult to detect bias in these types of publications than in reports of original research.”**

—International Committee of Medical Journal Editors (February 2006)





## Addressing conflicting interests: review article authorship at *The Lancet*

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“For Comment, Seminars, Reviews, and Series, *The Lancet* will decide not to publish if an author, within the past 3 years, and with a relevant company or competitor, has any stocks or shares, equity, a contract of employment, or a named position on a company board; or, in general, holds (or is applying for) a relevant patent (for the life of the patent); or has been asked by any organisation other than *The Lancet* to write, be named on, or to submit the paper (see *Lancet* 2004; 363: 2-3).”

— *The Lancet*

“It only needs the perception, let alone the reality, of financial conflicts and commercial pressures to destroy the credibility of important organisations such as IARC and its parent, WHO.”

— *The Lancet* 361: 189 (2003)





# Addressing conflicting interests: U.S. National Academy of Sciences

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**“In selecting members for a study committee, the Academies examine three aspects of the backgrounds of candidates:**

- relevant expertise,
- possible conflicts of interest, and
- potential sources of bias.”

**“Provisionally appointed committee members found to have conflicts of interest are typically removed from the committee and replaced with someone else with comparable expertise.”**

— National Academy of Sciences





# Addressing conflicting interests: some guidelines



TYPE OF CONFLICTING INTEREST	THRESHOLD FOR CONCERN	PERIOD OF RELEVANCE
EMPLOYMENT by an interested party	All	1 year with no collaborations
CONSULTING on matters before a court or government agency	All	3 years
CONSULTING on new products or process changes	2% of professional time or compensation	1 year
SPONSORED TRAVEL or sponsored presentations at scientific meetings	2% of professional time or compensation	1 year
RESEARCH SUPPORT for the expert's own research	All	1 year after last publication
RESEARCH SUPPORT for the expert's research unit	5% of research budget	1 year after last publication
STOCK and other financial instruments	\$10,000	Current interests only
PATENTS and other intellectual property	All	Current interests only



## Addressing conflicting interests: verification by a trusted neutral party

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For more than two years, IARC has provided for independent neutral-party verification of the conflicting interests of its experts

- IARC identifies experts, reviews their conflicting interests, then invites experts to a meeting
- At the meeting, IARC distributes a conflict-of-interest form used by *The Lancet Oncology*
- IARC collects the completed statements and sends them to *The Lancet Oncology*
- The editor of *The Lancet Oncology* reviews the conflict-of-interest statements and discloses any conflicting interests alongside IARC's published summary of the meeting (6-8 weeks after each meeting)





## **“Best experts” or impartial experts: two competing ideals**

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**What to do when an expert with relevant knowledge and experience also has a real or apparent conflict of interests?**

**This issue has become more visible in recent years, as interested parties increasingly sponsor epidemiological and experimental studies, or re-analyses of earlier studies**

**The selection of experts with real or apparent conflicts of interests can erode confidence in the integrity and impartiality of the results**

**On the other hand, the omission of prominent experts can create a perception of reduced scientific quality**





# “Best experts” or impartial experts: IARC’s solution

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IARC strives to achieve both ideals, through a category of participant known as an “Invited Specialist”

An Invited Specialist is an expert with critical knowledge and experience who is recused from certain activities because of a conflicting interest

- Do not serve as chair
- Do not draft text that describes or interprets cancer data
- Do not participate in the evaluations

Invited Specialists are available at IARC meetings to contribute their unique knowledge and experience

Thus, IARC meetings can include the best-qualified experts, and *IARC Monographs* are developed by experts with no conflicting interests





## **“Best experts” or impartial experts: advice from an IARC Advisory Group**

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**“The Advisory Group recognized the importance of using Invited Specialists as a resource for technical information that may assist a Working Group in its deliberations. However, because of the potential for conflict of interest, the Advisory Group recommends that Invited Specialists continue to be used by IARC in a limited capacity, and that their involvement be structured in such a way so as not to influence the evaluations. In this context, the Advisory Group felt that the role of Invited Specialists in drafting text for the Working Group should be restricted to non-influential issues in exposure such as a general description of data on production and use.”**

**—Advisory Group to Review the Amended Preamble (Dec 2005)**



# Freedom from interference: some measures used at IARC

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IARC posts a list of participants two months before each meeting, and to discourage interference we advise:

"IARC requests that you do not contact or lobby meeting participants, send them written materials, or offer favours that could appear to be linked to their participation. (You may send pertinent written materials to IARC.) IARC will ask participants to report all such contacts and will publicly reveal any attempt to influence the meeting. Thank you for your cooperation."

— *The Lancet Oncology* 6(10): 747 (2005)

IARC reminds participants to safeguard the integrity of everyone's work by resisting and reporting all attempts at interference

- In the invitation letters
- During the meeting

"It is not acceptable for Observers or third parties to contact other participants before a meeting or to lobby them at any time."

— Preamble to the *IARC Monographs*







# Freedom from interference: one reaction

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“ . . . an important step towards restoring trust in the way that results of studies done by publicly funded agencies are both prepared and reported. The issues encountered by IARC are certainly not unique and we hope that this joint initiative will serve as a model for other health agencies.”

— *The Lancet Oncology* 6(10): 735 (2005)





# It's important to remain vigilant: some new trends

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**Negative re-analyses of positive studies**

**Late-breaking scientific conferences and special journal supplements sponsored by special interests**

**Payments disguised as travel reimbursements**





# Summary

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## **It is possible to do good science while avoiding conflicts of interests**

- Send the message that you take conflicting interests seriously
- Identify conflicts by asking specific, objective questions . . . then verify!
- Look for repeated activities that suggest an ongoing relationship with interested parties
- Address conflicts consistently, swiftly, and with transparency
- A trusted neutral party can verify conflicting interests

## **It is possible to have the “best experts” while reserving critical functions for those without conflicting interests**

## **Additional measures can be taken to keep meetings free from interference**

## **These approaches have been working well at IARC for the past 2-4 years**





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