



Online Ethics Center
FOR ENGINEERING AND SCIENCE

Topics: Conflicts of Interest

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Description

A guide that provides information and resources on teaching responsible conduct of research that focuses on the topic of conflicts of interest. Part of the Resources for Research Ethics Education collection.

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Summary

What is a conflict of interest?

We often find ourselves faced with two or more competing interests, creating the perception, if not the reality, of an **increased risk of bias or poor judgment**.

We are most familiar with financial conflicts. For example, a researcher could be studying a new product for which they will receive significant financial rewards if their studies result in positive findings. However, conflicts can come from many other competing interests, such as career advancement or responsibilities to family or friends.

What should you do?

- **Comply with regulations**

Researchers should ask about and adhere to institutional and governmental requirements for identifying, disclosing, and managing conflicts of interest.

- **Avoid and minimize conflict**

Although it is not possible to avoid all sources of conflict, it is in the best interests of the scientific community and of individual scientists to recognize conflicts of interest and to take steps to nullify or mitigate those conflicts.

- **Disclose interests**

If conflicts cannot be avoided, then those conflicts should be disclosed. At minimum, the institution and any other parties with a significant interest should be made aware of the extent and nature of the conflict.

- **Manage conflicts**

Disclosure is often not enough. For every step of the research process, attempts should be made to isolate the conflicted individuals from all decision-making functions.

- **Keep learning**

Both the potential for conflicts of interest and the strategies for dealing with those conflicts are evolving. Considering the potential for misperceptions of a researcher's motives, it is best to assume that good intentions are not enough. Seek out information so as to comply with the spirit and letter of current regulations.

Background

Overview

- We often find ourselves in situations where two or more competing interests create the **perception -- or the reality -- of an increased risk of bias or poor judgment.**
- Collectively, we refer to these challenging situations as **conflicts of interest.**
- Scientists have professional, fiduciary, and ethical interests in the responsible conduct of research, but these interests may be **compromised by personal interests.**
- Such conflicts are **not inherently bad.** Indeed, they are to be expected. It's how they are handled that can lead to improper, inappropriate, or bad outcomes.

Financial vs. Non-Financial Conflicts

A common worry is that **financial interest** in the outcomes of research can result in unethical behavior or even criminal misconduct.

However, it is also plausible that **interests other than financial interests** could compromise the responsible conduct of research.

Examples of non-financial interests that might conflict with the integrity of science include:

- career advancement
- publishable results
- service to patients or students
- fame
- power
- family and friendships

Conflicts of Conscience

Another potential conflict can come in the form of conscience. An individual might suffer a conflict of conscience if, for example, the mission or expectations of the institution are incompatible with his or her personal values.

Risks of Conflicts of Interest

Risks of conflicts of interest are not merely hypothetical. Financial conflicts are associated with altered outcomes of research. For example:

Stelfox et al. (1998) reviewed the literature in 1995 and 1996 for reports on the safety of calcium channel antagonists. They classified reports as being supportive, neutral, or critical of these drugs. For reports supportive of calcium channel antagonists, virtually all authors had financial relationships with drug companies. However, only 43% of the authors of reports critical of the drugs had such connections with drug companies. Many different hypotheses might explain this trend, but it seems clear that it would be valuable to know if a published study was supported by industry.

Intentional Bias: Is it Research Misconduct?

Conflicts of interest do not necessarily amount to research misconduct. However, if the potential for personal gain is great, then principles that guide responsible conduct in research may be compromised. In an extreme case, it is conceivable that

someone could **knowingly compromise principles of good scientific practice** in pursuit of a particular research finding our outcome.

Unintentional bias

Conflicting interests are more likely to result in unintentional rather than intentional bias. For example:

- **Choices of topics, methods, and approaches** may be made based on availability of financial support rather than the best science or the greatest needs.
- In the **design of experiments**, scientists may be unconsciously biased to choose, or stick with, approaches likely to provide *marketable* findings, rather than those designed to increase basic understanding of mechanisms.
- In the **collection of data**, a researcher with significant financial interests may unwittingly introduce bias into enrollment of subjects for a clinical trial, into evaluation of data dependent on subjective judgments, or even into the reading of objective measurements.
- Choices for **data selection, statistical methods, and presentation of results** could be affected by unintentional bias.

Unintentional bias can be a **more serious threat than deliberate misconduct**, because even those who are biased would be unaware of the ways in which their behavior had been altered.

Disclosure of Conflicts

Declaring that you have a conflict of interest is typically called **disclosure**.

In practice disclosure of research conflicts usually occurs only for financial interests. Historically, such disclosure was not routine, even in the biomedical literature (Krimsky and Rothenberg, 2001):

In a survey of 789 scientific papers published by Massachusetts scientists in the leading journals of cell and molecular biology, 34% of the articles had at least one author with a significant financial interest. Despite this high rate of financial interests, only about 0.5% of over 61,000 comparable papers included disclosure statements.

Today, most journals require disclosures of financial conflicts. Disclosure not only alerts readers to the increased possibility of unintentional bias, but it could strengthen the resolve of an individual researcher to choose research designs that minimize the risk of their bias.

Perceptions may outweigh even the best of practices

When large sums of money are involved, it may be difficult for the public, legislators, the judicial system, and even colleagues to be convinced that results were not biased for personal gain.

Perceived impropriety can result in consequences as damaging as if intentional misconduct had been committed.

With **increased media, governmental, and public scrutiny**, a researcher's reputation, research funding, and employment can depend as much on perceptions of integrity as on integrity itself.

Regulations and Guidelines

A variety of regulations and guidelines govern the disclosure and management of conflict of interest. Although many concerns could be generalized to any form of conflict of interest, the focus of regulations tends to be financial. The most relevant of these are federal regulations, notably those of the Public Health Service (PHS) and National Science Foundation (NSF).

*According to the Code of Federal Regulations (PHS, 2011), the **PHS conflict of interest requirement** "promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health Service (PHS) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest." Investigators are required to disclose any **Significant Financial Interests**, which are defined as:*

- "any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds **\$5,000**."
- "**Intellectual property** rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests."
- "the occurrence of any reimbursed or sponsored **travel** (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities."

NSF conflict of interest requirements (NSF, 2021) are largely similar although current guidelines set a threshold of **\$10,000 for a significant financial interest**. Individual institutions and organizations may choose to adhere to the stricter PHS standard of \$5,000.

Professional societies and journals are another important source for guidance on the management of conflicts of interest. These are quite variable in their scope and not always enforced, but three examples are noteworthy:

1. Requirements for publication in the **New England Journal of Medicine**. As early as 1984, the journal requested that "*all authors disclose to [the Editor] any associations they had with businesses that could be affected by their work -- including direct employment and consultancy, stock ownership, and patent-licensing arrangements.*" (Angell and Kassirer, 1996).
2. Policy statement from the **American Society of Gene Therapy** (ASGT). The ASGT concluded that "*investigators and team members directly responsible for patient selection, the informed consent process and/or clinical management in a trial must not have equity, stock options, or comparable arrangements in companies supporting the trial.*" (Woo, 2000).
3. Guidelines from the **Association of American Medical Colleges** and the **Association of American Universities** (AAMC-AAU, 2008)
This report resulted in 15 recommendations to address conflicts of interest

through the roles and responsibilities of individuals, institutions, and at the federal government.

These guidelines and regulations represent a recognition by regulatory and scientific communities that the integrity of science is placed at risk by the presence of unmanaged or substantial conflicts of interest.

Discussion

Case Study 1

Dr. Mitchell Conrad has received a grant from an industrial source to do basic research that has long-term implications for commercialization. A new graduate student, Michelle Lawless has just joined his lab following the completion of one semester of graduate coursework. Dr. Conrad outlines several projects that can be pursued by Michelle under this industrially-sponsored research program. Dr. Conrad indicates that there is a proviso listed in the industrial grant agreement which says that all material to be submitted for publication first be reviewed by the company. This review must always be completed within 120 days. Dr. Conrad points out that this presents only a minimal disruption to the normal publication process as compared to the unrestricted publication of material gathered under federal research grants. He also mentions that the positive aspects of working on this proposal include the fact that there is money in the grant for Michelle to travel to at least two meetings per year. Also the grant application provides money for a personal computer that will be placed at Michelle's lab station while she is working on the project. Dr. Conrad emphasizes that working on the project will likely give Michelle an "inside track" with the company should she want to pursue job possibilities there following graduation. Michelle agrees to work on the project. Comment on the ethical and conflict of interest implications of this scenario.

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Case Study 2

Dr. Wilkins has a modest research program supported by a grant from a local foundation. Wilkins brings a personal check for \$3,000 into the office of Mr. Cole, the departmental administrator, and says that it is a gift which may be used by the department at the discretion of the chair. When Mr. Cole consults with Dr. Vaughn, he learns that Dr. Vaughn and Dr. Wilkins have already discussed this arrangement.

Dr. Vaughn says she has agreed to let Dr. Wilkins spend this money as it will help him strengthen his research program to the point where he'll be able to successfully compete for federal grants. Over the course of the next several months Dr. Wilkins uses some of the money to purchase a new computer and printer which he installs in his home. He uses the remainder of the money to attend a meeting in his research field. At the end of the year Dr. Wilkins donates \$5,000 to the department. Over the next several months he uses this money to attend two other meetings, and to pay for several subscriptions to scientific journals, and to an electronic database subscription. Comment on any conflict of interest considerations of this scenario.

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Case Study 3

Mr. Asset, a graduate student of Dr. Bond, has been conducting physicochemical studies on the properties of a new polymer. The research is sponsored by Chemical Industries, Inc. and it is understood by Mr. Asset and Dr. Bond that the results are proprietary, confidential, and cannot be used in Mr. Asset's thesis. Mr. Cash, the technical liaison from Chemical Industries, Inc., meets with Mr. Asset and Dr. Bond and expresses his pleasure with the outcome of the recent studies and observes that the new results are the last data required to market a new generation of fire-resistant electrical insulating material. Mr. Cash further comments that this is the product that Chemical Industries, Inc. needed to regain its market share, and the stock of Chemical Industries, Inc. would soar once investors knew of the new product. That evening at dinner with his wife and brother-in-law, an investment banker, Mr. Asset tells them about Mr. Cash's enthusiasm about their recent research results and Mr. Cash's expectations that Chemical Industries' stock would greatly increase in value as soon as the new product was announced. The next day Mr. Asset's brother-in-law advises several of his clients to purchase Chemical Industries' stock. Did Mr. Asset breach his confidentiality agreement by discussing his research results with his wife and brother-in-law? Does Mr. Asset profit by the disclosure of the research results that will increase the value of the stock of Chemical Industries, Inc.? Discuss a scientist's responsibility for maintaining the confidentiality of research results.

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Discussion Questions

- Define conflict of interest.
- List and describe three distinct conflicts of interest that are not financial.
- What interests, other than financial, do you have in obtaining positive results in your research?
- Why is a financial conflict of interest not necessarily considered to be misconduct? Discuss circumstances under which a financial conflict of interest might result in misconduct.
- If you were reading the work of another scientist, then what, if anything, do you need to know about interests of that scientist that might be in conflict with a published work? If it were relevant to the subject of the paper, which of the following would you want to know about an author's interests:
 - a. Financial stake (e.g., ownership, stock, stock options) in a company that markets the product discussed in the paper
 - b. Financial stake (e.g., ownership, stock, stock options) in a company that markets a product similar to the one discussed in the paper
 - c. Previous support (e.g., research materials, grants, or contracts) from a company that markets the product discussed in the paper
 - d. Current or previous role as a consultant with a company that markets the product discussed in the paper
 - e. Physical or psychological conditions (e.g., depression or diabetes) of the author that are also the subject of the paper
 - f. Sexual orientation of the author for research that excludes, or includes, a genetic basis for homosexuality

Resources

- [OEC Conflict of Interest Bibliography](#)
A bibliography of books, online resources and articles on conflicts of interests.
- [Best Practices for Publishing Your Research: Conflict of Interest](#)
An instructor's guide, slide deck, and video for the teaching module looking at conflicts of interest in scientific publication.

Cited Resources

1. AAMC-AAU Advisory Committee on Financial Conflicts of Interest in Human Subjects Research (2008): [Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects Research](#). AAMC.

2. Angell M, Kassirer JP (1996): [Editorials and conflicts of interest](#). New England Journal of Medicine 335(14): 1055-6.
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4. Krinsky S, Rothenberg LS (2001): [Conflict of interest policies in science and medical journals: Editorial practices and author disclosures](#). Science and Engineering Ethics 7:205-218.
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Notes

The Resources for Research Ethics Education site was originally developed and maintained by Dr. Michael Kalichman, Director of the Research Ethics Program at the University of California San Diego. The site was transferred to the Online Ethics Center in 2021 with the permission of the author.

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