Conflicts of Interest (RCR-Basic)

Introduction

Learning Objectives

- Define different types of conflicts of interest.
- Define conflict of commitment.
- Explain the reasons why conflicts of interest and commitment can be problematic.
- Discuss U.S. regulations and policies relating to financial conflicts of interest.
- Describe strategies that may mitigate or eliminate the impact of conflicts of interest.

Definitions

Notional Academics (2003) defines conflict of interest as:

"Any financial or other interest which conflicts with the service of the individual because it (1) could significantly impair the individual's objectivity or (2) could create an unfair competitive advantage for any person or organization."

Figure 1: Conflict of interest

The possibility that one's actions could be biased is enough to generate a conflict. Another way to define a COI is if an outside observer might possibly think that a person's judgement or objectivity could be biased by the situation.

Financial Conflict of Interest

Type of financial interests that could create a conflict are included in Figure 2:

Both the financial interest and the research related to that interest must be present for there to a conflict of interest. Ways to determine this include whether:

Institutional Conflicts of Interest

Institutional COIs, also called organizational COIs, can be financial or non-financial in nature. For example, an academic institution might hold financial interests in companies that sponsor research at the institution. These financial interests can be in the form of stock holdings in an investment portfolio, gifts to the institution, or royalty payments from the company to the institution.

Non-Financial Conflicts of Interest

Conflicts of interest do not have to have a financial component to influence objectivity. There are many types of non-financial conflicts. For example, academic conflicts of interest include becoming overly attached to a specific research outcome. This can result in a phenomenon referred to as confirmation bias, where data which do not support one's preconceptions are inappropriately discarded and data which do are over-valued.

Stock ownership in a public or private company

Receipt of payment for services including consulting work

Receipt of intellectual property rights or royalties

Figure 2: Types of conflict of interest

The company sponsors the research

The company owns materials, specimens, or intellectual property under study

The company may be affected financially (positively or negatively) by the research

Figure 3: Ways to determine a conflict of interest exists

Conflicts of conscience occur when personal beliefs might interfere with objectivity. For example, a conflict of conscience can emerge when examining a controversial topic that has moral dimensions, such as embryonic stem cell research or certain forms of military research. The nature of the topic has the potential to bias judgment.

Personal conflicts of interest can occur when someone supervises or makes work-related decisions involving a relative, friend, or close acquaintance. For example, participating in the hiring decision of one's spouse creates a personal conflict of interest. Another example is deciding whether a close relative should be admitted into a graduate program. In short, the personal relationship might influence a decision that needs to be made fairly and objectively.

Conflicts of Commitment

Conflicts of commitment, also referred to as conflicts of effort or obligation, arise when paid or unpaid outside activities could interfere or have the appearance of interfering with the commitment to one's primary employer. The main concern emerging from conflicts of commitment is whether sufficient time is being dedicated to one's professional duties. This is in contrast to other conflicts of interest where the main concern is about the possible introduction of bias when performing those duties. Conflicts of commitment can result in a loss of productivity, which can damage one's career and have a negative effect on collaborators.

Why Conflicts of Interest are Problematic

Introducing bias or the appearance of bias

Increasing the possibility that the results or the presentation of the research will be called into question

Damaging professional or organizational reputation

Losing funding opportunities

Figure 4: Ways conflicts of interest can affect research

Policies and Regulations

Conflicts of interest are usually covered by organizational policies and by federal or state law. For example, state institutions may be subject to statutes that require annual disclosure of such conflicts. Similarly, organizational policies often include stipulations about:

- What constitutes a conflict
- What needs to be disclosed
- I How it needs to be disclosed and to whom
- **■** What activities are permissible
- I How conflicts should be managed or eliminated

Figure 5: Organizational policy stipulation examples

It is always the responsibility of the individual with the conflict to disclose it to the organization.

The National Institute of Health (NIH) and COISs

The U.S. Public Health Service, which encompasses the National Institutes of Health (NIH), has detailed regulations that require annual disclosure of any related financial interest, subject to monetary thresholds, from all investigators who propose, conduct, or report research funded by the agency (NIH 2018). The investigators must disclose the information to their organization, which then has to review and manage any conflicts of interest.

Other U.S. Funding Sources

In general, federal sponsors require disclosure and management of COIs. Noncompliance with these terms can result in suspension or termination of a sponsored project (NIH 2015).

Managing Conflict of Interest

Anyone who is in a situation that could rise to the level of a conflict should refer to organizational conflict of interest policies and consult with a supervisor or administrator to determine the best way to proceed.

A financial conflict of interest could involve a small one-time payment or result from multiple, substantial payments over a period of time. One measure of the severity of the conflict is the amount of the financial interest (in general, the larger the payment, the greater the likelihood of bias). Some financial interests are difficult or even impossible to quantify. For example, if a researcher has equity in a start-up company and the company does well, the equity could be worth millions. If the company does poorly, the equity could be nearly worthless.

Another way to judge the severity of a conflict of interest is to look at the stage of the research. For example, if a researcher is about to bring a product to market and not at the beginning stage of a project, there is greater possibility for financial gain. This may intensify a conflict and require additional management or elimination.

Management Strategies

Common methods used to manage or eliminate COIs in research include:

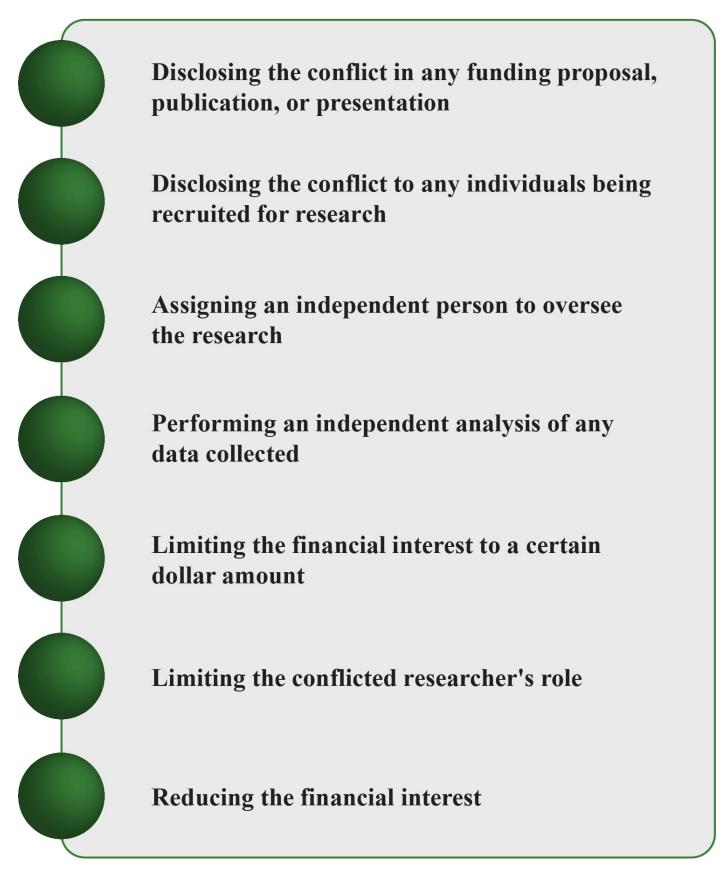


Figure 6: Common methods to manage or eliminate COI's