

Some Dos and Don'ts in conflicts of interest and commitment

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Thousands of patients are fighting diseases everywhere in the world. Science and medicine are not sometimes moving fast enough to save them.

We lose loved ones everyday.

To those who lost the battle and left us...

We are trying to do this right, for you and for thousands of patients who are still struggling.

Please take a minute to fill this survey

- <https://goo.gl/forms/4yRHeF3S1auycYZN2>

- The NIH director, Dr. Francis Collins stated that “the public trust in what we do is just essential, and we cannot afford to take any chances with the integrity of the research process”.

Description

This session will discuss **what constitutes** conflict of interest, different **types** of conflicts, and **how** conflict of interest can be **best managed**.

Learning Objectives

By the end of this module, you should be able to:

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

Definitions

Conflict of interests (COI):

- An actual conflict of interests (COI) occurs when **one's personal interests or those of an immediate family member or a close relative**, be these interests **financial, political, professional** or otherwise, **can compromise the judgment or the performance** of one's job responsibilities.
- COIs are **not necessarily a bad** behavior; however they are situations that **must be disclosed**. In some circumstances, the situation could reflect a **potential COI or could be perceived as COI** and these also need to be disclosed.

- A COI occurs even if there is a situation that can potentially impair the judgment of a researcher, **regardless of whether the judgment was actually impaired or not.**
- Similarly, a COI arises if an **outsider can surmise** from a particular situation that the judgment of the researcher could be biased as a result.

Because COI could

- (1) significantly **impair** the individual's **objectivity** or
- (2) create an **unfair competitive advantage** for any person or organization.

- COIs can **impact the design or conduct** of a study, as well as the **analysis or reporting** of any results.
- For example, conflicted researchers might decide to **delay or choose not to publish** results if they believe that **benefits can result** from doing so.

Examples of COIs:

- using **university resources** (e.g. computers, printers, phones, etc) for **personal purposes**.
- **purchasing personal items** on a **university account**.
- dispensing of **old university property** without prior authorization.
- receiving **gifts** or sponsorship from an actual or potential **vendor** without prior approval.
- receiving research **funds from an industrial** entity, while **serving on their board, without disclosure**.
- **stock ownership** in a public or private **company sponsoring** one's research
- receipt of **payment for** services including **consulting work** for a company that **provides materials or equipment** used in one's **studies**.
- receipt of **intellectual property rights or royalties**.

- A researcher who **starts a company to commercialize** a product prepared in his lab, **forcing students to work** for that purpose which **might take time from their academic** work.
- A researcher who **publishes a series of papers with little input** to advance his academic record **instead of one bigger publications** of more scientific impact.
- A researcher who accepts a **grant that is financially beneficial** but **not scientifically so** for his team.

- A **physician** who provides **health services** to the employees of a certain **company** while being the **PI of a clinical trial** to test a new **product of the company**.
- **Students** working on a **research project funded** by a **company** while receiving **internships** from the same company. **Negative results** might **affect any future employment** at that company.

Real life COI stories

- the **Environmental Protection Agency** determined in 1993 that “**environmental tobacco smoke**” should be classified as a **Class A carcinogen**.
- **Tobacco industry** memoranda concluded that the possible **banning of smoking in public places** would **reduce cigarette consumption and profits**.
- In response, **the tobacco industry** created a **nonprofit organization**, the **Center for Indoor Air Research**, to **fund** well over **200 published** studies to **counter the EPA finding**.
- Additional steps included:
 - (1) formation of a **consultant program funded by U.S., Japanese, and European tobacco companies** to present **favorable findings** at **scientific meetings** and to **publish** findings;
 - (2) **introduction of bias** into studies by **misclassification of study subjects** to **reduce the apparent impact of secondhand smoke**;
 - (3) placement of **industry in-house scientists** on **journal editorial** boards.

This history of tobacco company funding does **not mean that all industry-funded research is tainted**. Companies, however, **tend to fund** external product studies that are likely to be **favorable** to them. This predisposition points toward the need for **strong conflict of interest policies** to **minimize bias**.

- **Patricia Buffler** was a **dean of the School of Public Health at the University of California, Berkeley**. She started the **US' largest** program researching the causes of **childhood leukemia** and was hailed as a **champion of children**. She worked on this project till her death in 2013.
- Her work showed **strong evidence** that **preschoolers** should **stay away from wet paint** (for fear of lead poisoning).
- The **scientific community was shocked** to learn afterwards that **Buffler** was paid more than **\$360,000** to work as an **expert witness** on behalf of **companies** that used to sell **lead based paint**.
- Researchers familiar with her chemical industry consulting question **whether she bent to the wishes of her corporate sponsors** — a criticism she **denied** when questioned in lawsuits.
- Her **dual career** as **public health researcher** and **consultant for private industry** — opens a window into the deeply entrenched **influence of the chemical industry on academics**.
- In addition, Even as Buffler led **research into whether pesticides and herbicides may cause leukemia**, she served for **17 years on the board of directors of a pesticide and herbicide company** and was nearly paid **\$200,000 in cash and stock**.
- Buffler **did not disclose** that she owned stock in this company or served as one of its directors.

- **UC Berkeley officials knew** that Buffler served on the company's board.
- And until **federal rules changed** recently, it was **up to researchers to decide whether their financial ties posed a conflict**. The university limited its own review to potential conflicts the researchers disclosed before forwarding the grant application to the NIH.
- **Graham Fleming, the school's vice chancellor for research wasn't willing** to say whether **Buffler serving on the board posed a conflict**. He surmised that **given Buffler integrity** throughout her career, she **must have determined** that there was **no conflict**.
- **Sheldon Krinsky, a Tufts University professor** and an **expert in conflicts of interest** in scientific research, said after reviewing Buffler's case, "This is **the worst case of conflict of interest** I've seen in years."

The Enstrom and Kabbat paper exercise

Other forms of COI

- [Academic COI](#): when a scientist becomes **fixated** on a certain finding, **discarding** any data that **contradict** this finding and **emphasizing** those that **support** it (**confirmation bias**).
- **Conflict of conscience**: when one's **moral or religious** standings might **interfere** with their **objectivity** regarding a certain topic as in **embryonic stem cell research**.
- **Personal conflict of interest**: when one's **personal relationship** might **affect their decision in a research related manner**, as in **recruiting** one's **sick relative** in a **clinical trial** for a new treatment.

Examples

- the **ideological rejection of Mendelian genetics** in the **Soviet Union** beginning in the **1930s crippled Soviet biology** for decades.
- The field of **eugenics** used the techniques of science to try to **demonstrate the inferiority** of particular human groups, according to **nonscientific prejudices**.

Conflict of commitment (conflicts of effort or obligation):

- A conflict of commitment occurs when the **performance** of one's **external activities limits the time or resources** one dedicates to carrying out **one's institutional job**.
- This is mainly because there is a concern as to whether the **extra duties** might put time **constraints** on the person's ability to perform **their primary duties**. This can **diminish** the person's **productivity**, affecting their career.

Examples

- Post graduate **students** working on **different projects** including some **not related to** their **thesis** work, interfering with the amount of time they can dedicate to their thesis.
- Professors giving **lectures at an outside organization** limiting the time available to carry out their primary academic duties.
- However, **participation in conferences and lectures or scientific meetings or serving on the editorial boards of scientific journals or government advisory boards** are **not** considered as **conflict of commitment**.

A fictional case of Conflict of Commitment

- **Sandra is a graduate student** in the laboratory of **Dr. Frederick**, a leading scholar in her field. The **project** on which she was working was **totally supported by a grant from a single company**.
- She had **asked Dr. Frederick** about this **before coming** to his lab, and he had **assured her** that he did **not think** that the **company's support would conflict** with her education.
- But the more **Sandra worked** on the project, the more it seemed **skewed toward questions important to the company**. For instance, there were so **many experiments** she needed to carry out **for the company's research** that she was **unable to explore some of the interesting basic questions raised by her work** or to **develop her own ideas** in other areas.
- Although she was **learning a lot**, she worried that her ability to **publish** her work would be **limited** and that she would **not** have a **coherent dissertation**.
- Also, she had heard from some of the other graduate students doing **company-sponsored work** that they had **signed confidentiality statements** agreeing **not to discuss their work with others**, which made it **difficult to get advice**.
- **Dr. Frederick and the company's** researchers were very **excited about her results**, but she **wondered** whether the situation **was the best for her**.

1- Has Dr. Frederick done anything wrong in giving Sandra this assignment?

2- What potential conflicts in terms of data collection, data interpretation, and publishing might Sandra encounter as she continues with her research?

Why conflicts of interest are problematic?

- They can either **bias or appear to bias the judgment** of researchers.
- Can introduce an **element of mistrust** in the findings of a study.
- Can affect the integrity of **peer reviewing** process.
- Can **damage professional reputations**.
- **Termination** of positions and **loss of funding**.

“There are systematic and predictable ways in which people act unethically that are beyond their own awareness,” and that “self-interest unconsciously biases well-intended people, who give themselves bounded 'moral wiggle room' to engage in unethical behavior with an easy conscience”.

“The Scientific Basis of Influence and Reciprocity Symposium.”

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COI policies

- The damage can be **mitigated** if the COI was **disclosed** and properly **managed**.
- Most organizations have **policies** to manage COI.
- These policies usually cover:
 - **what is** construed as a **conflict**
 - **what needs to be disclosed** and the **mechanism** to do that
 - The **frequency** of disclosure
 - what activities are **permissible**
 - how to **manage** and if possible eliminate conflicts

- The **management** of COI depends on the **nature and severity** of the COI (**larger sums of money** received for a certain consultancy job for instance present **more of a conflict** than smaller sums). Also the **stage (closer to marketing)** and **nature (human vs in vitro)** of research is an important **factor** in determining the **management** of COI.

Management of conflicts

- It is the **responsibility of the researcher** to **disclose any COI** or potential COI and to **discuss** it with their **supervisors** or those in charge.
- It is better to discuss COI and potential COI **early on** than to report an actual COI later.
- The organization appoints a **committee to review the potential COI** and decide if the conflict is **manageable**.
- A management **plan is devised** and should be **agreed upon with the person experiencing the COI and the organization**.
- Such **policies** have to be **announced** to staff members at the organization in advance (**upon joining** the organization with **periodic reminders**).

Management plans can take the form of, but are not restricted to:

- public **disclosure of financial** interests.
- **modification of the research** plan.
- **recusing** the staff member from participating in **certain stages** of a study.
- requesting independent **external reviews** for the work.
- **termination** of certain **suspicious relationships**.
- **Disclosure** of the conflict to the **human participants** in a study.
- **Limiting** the financial interest to a **certain sum of money**.
- **Conflicts of commitment** can be managed by **limiting the time** dedicated to outside activities or by allowing the researcher to take a **leave of absence**.

- **Disclosing and managing COI** has the benefit of increasing **transparency** and **ensuring** funding organizations and tax payers of the **integrity** of research institutions.
- It gives **outsider** readers and reviewers the **chance to evaluate** for themselves whether a **bias might have occurred**.

Please take a minute to fill this survey

- <https://goo.gl/forms/hwo6rq2yJwf2TAu23>

References

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- Conflict of interest policy prepared by Mariam Abbas, Iman Amrani, Manek ben Ferej and Alaa Abouelfetouh under mentorship of Dr. Kenneth Goodman (week 5 assignment in winter semester).
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- Tong E. K. and Glantz S. A. (2007). Tobacco Industry Efforts Undermining Evidence Linking Secondhand Smoke with Cardiovascular Disease. *Circulation*. 116: 1845-1854.
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Awareness of COI among researchers

	Before (n=10)	After (n=7)
No COI if no impairment of judgment	% (False)	% (False)
COI of a spouse	% (Yes)	% (Yes)
Definition of COI (work for X and fund from B)	% (No)	% (No)
Definition of conflict of commitment	% (No)	% (No)
Awareness of Alex Univ conflict of commitment limit	% (Yes)	% (Yes)
Reason to disclose conflicts	%	%
Problems of not disclosing	%	%
Definition of COI	% (Yes)	(Yes)
Management of COI	% (submit, disclose and be excused)	% (submit, disclose and be excused)

Thank you