“Conflict of Interest and Collaborative Science: An Overview”

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Meet Your Colleagues
Thank You for Being Here Today!

Charles Darwin

Albert Einstein

Antoine Lavoisier
Father of Modern Chemistry

Albert W. Overhauser, Purdue
“Dynamic Nuclear Polarization”

South Korean stem cell researcher Hwang Woo-Suk
Overview of Presentation

• Define conflicts of interest and explain governing policies and procedures
• Discuss a variety of ethical issues encountered by researchers and research administrators in order to better identify and manage conflicts of interest
• Describe collaborations between academia, government and private industry in research and the conflicts of interest that may arise from these relationships
Responsible Conduct of Research (RCR)

The Office of Research Integrity (ORI) is organized under the U.S. Department of Health and Human Services (HHS), the Office of the Secretary of Health and Human Services (OS), and the Office of Public Health and Science (PHS).

ORI describes education and training in responsible conduct of research (RCR) in terms of nine instructional areas:

1. Data Acquisition, Management, Sharing & Ownership
2. Conflicts of Interest and Commitment
3. Human Subjects
4. Animal Welfare
5. Research Misconduct
6. Publication Practices and Responsible Authorship
7. Mentor / Trainee Responsibilities
8. Peer Review
9. Collaborative Science
NSF Agency Specific Requirements Responsible Conduct of Research

• … NSF requires that grantees must have a plan in place to provide appropriate training and oversight in the responsible and ethical conduct of research (RCR) to undergraduates, graduate students, and postdoctoral researchers who will be supported by NSF to conduct research. Training plans are subject to review, upon request.

• … Grantees must designate one or more persons to oversee compliance with the RCR training requirement.

• … Grantees are responsible for verifying that undergraduate students, graduate students, and postdoctoral researchers supported by NSF to conduct research have received training in the responsible and ethical conduct of research, in accordance with the plan the grantee has put in place for their organization.

• … Grantees shall ensure that these RCR requirements flow down to all subrecipients, or are otherwise appropriately addressed in the subaward instrument.

Conflicts of Interest and Commitment

“An individual has a conflict of interest when he or she has personal, financial, professional, or political interests that are likely to undermine his or her ability to meet or fulfill his or her primary professional, ethical, or legal obligations.”

- Shamoo & Resnick, 2009
Actual vs. Perceived Conflict of Interest

“An individual has an apparent conflict of interest when he or she has personal, professional, or political interests that create the perception of a conflict to a reasonable outside observer.”

- Shamoo & Resnick, 2009
Scientific Objectivity

• A variety of financial, personal and political interests can create conflicts of interest, or the appearance of conflicts of interest, for researchers and research institutions

• These interests may compromise the integrity and trustworthiness of the research enterprise
Objective of Conflict of Interest Policy

• To protect the integrity of the research process, and
• To promote trust in response to actual or perceived conflicts of interest
A Balancing Act

Scientists have personal, financial and political interests
- Career ambitions
- Quest for reputation, fame, power
- Priority of discovery
- Funding
- Publication
- Tenure
- Promotion

Scientists have professional and ethical responsibilities
- Colleagues
- Students
- Sponsors
- Employers
- Clients
- Patients
- Students
- Society
Possible Examples of Conflicts of Interest in Research

• An academic researcher with stock in an energy company that sponsors his research overestimates the significance of his research on one of the company’s products, which drives up the price of his stock

• A scientist receives orders not to publish results that are contrary to the interests of the company that funds her research

• A clinical investigator receives $3,000 in patient care costs for each patient she recruits into a clinical trial
Theory vs. Practice?

• A CoI can affect a person’s thought processes:
  judgment, perception, decision-making or reasoning
• A CoI can affect motivation and behavior:
  failure to implement sound thinking or succumbing to temptation
• Financial interests can bias the judgments and decisions made by investigators and can exert subconscious influences on thought processes (Katz et. al. 2003)
Literature Review

A substantial body of literature suggests a strong relationship between the source of funding and the outcome of research (Krimsky 2003, Angell 2004, Resnik 2007b)

- Review of 349 clinical trials; studies sponsored by pharmaceutical companies are more likely to favor company products than studies sponsored by government (Ridker & Torres 2006)
- Review of 37 papers on financial relationships and their influence on research found statistical significance between industry sponsorship and pro-industry results (Bekelman et. al. 2003)
- 95% of industry-sponsored articles on drugs used in cancer research reported positive results as opposed to 62% of non-industry-sponsored articles (Friedberg et. al. 1999)
Decision Factors

1. How strong are the interests involved and how likely are they to affect thought processes or behaviors?

2. How difficult is the CoI to manage and are there sufficient resources and mechanisms to do so?

3. What are the consequences of prohibiting or not prohibiting the CoI?
Key Concepts

• Conflicts of Interest are not inherently unethical. In fact, conflicts of interest often enhance research productivity.

• Bayh-Dole Act of 1980

• It is important to recognize the difference between actual and perceived conflicts of interest.

• The basic premise of CoI Policy is to ensure the integrity of the science by insulating it from potential adverse influences.

University of Utah Policy:

“...conflicts of interest exist when an individual’s personal financial interests could improperly influence execution of University responsibilities.”

“...are not inherently unacceptable, but must be identified and managed, reduced, or eliminated to prevent damage to the individual and the institution.”
Types of Conflicts of Interest

• Financial
  – ex/. a researcher with stock options in a pharmaceutical company conducting studies on that company’s drugs
  – University of Utah Policy defines a ‘significant’ financial interest as $10,000/year or 5% entity for the individual and/or an immediate family member

• Commitment and Duty
  – ex/. consulting relationships with other organizations, use of institutional resources for outside affiliations, allocation of time and attendance, respect of confidentiality

• Personal / Individual
  – ex/. signature authority for goods and services solicited by businesses owned by family or relatives, reviewing and recommending applications for hire from friends and neighbors, legislators receiving large gifts or honoraria from lobbyists

• Institutional
  – ex/. university officials own stock in a company that sponsors research on campus and provides large endowments
Bayh-Dole Act

Principles:
• Research discoveries may benefit the public good
• Public or private investment may be required to further develop and commercialize discoveries
• Intellectual property rights, such as patents and copyrights, provide protection for investment

Public Law 96-517 (1980):
• The Bayh-Dole Act created a uniform patent policy for all organizations accepting federal monies
Before Bayh-Dole Act (pre-1980)
After Bayh-Dole Act (post-1980)

Federal Government
- Funding
- Shared Title

Universities
- Licenses
- Sponsorship

Industries

Products

The Public

Income
Effect on Academic Patents

Bayh-Dole
Addressing Conflicts of Interest

Can a researcher balance the conflict of interest between seeking scientific truth and seeking potential profit?

• Management
  – Disclosure of the conflict to all appropriate communities
  – Establish a monitoring plan for by an objective superior(s)
  – Removing the conflicted individual(s) from relevant steps in the process (delegate the task(s) to non-conflicted parties)

• Reduction
  – Divestment below ‘significant’ level

• Elimination
  – Conflicted individual recuses self from the situation
  – Institution discontinues or suspends activity altogether
Examples of Ways to Manage Research Conflicts of Interest

• Disclosure of the conflict to supervisor and superiors
• Disclosure of the conflict in journals, publications and public presentations
• Disclosure of the conflict to research subjects, colleagues, students and subordinates
• Written acceptance of organization’s Conflict of Interest policy statement
• Delegate decision-making responsibilities to a non-conflicted member of the research team
• Monitoring of the research by a non-conflicted party(s) who is not a member of the research team
• Blinding of all data analysts; independent review
• Human subjects are consented by a non-conflicted party(s) who is not a member of the research team
Institutional Conflict of Interest

“An institution has a conflict of interest when its financial, political, or other interests are likely to undermine its ability to fulfill its professional, legal, ethical, or social responsibilities.”

- Shamoo & Resnick, 2009
University of Alabama in Huntsville

Conflict of Interest Policy

http://www.uah.edu/facsen/Faculty%20Handbook/APPENDI.htm
**Major Areas Addressed in the 2012 NIH Revised Regulations**

http://grants.nih.gov/grants/policy/coin/

- Definition of Significant Financial Interest (SFI)
- Extent of Investigator Disclosure
- Information Reported to PHS Awarding Component (e.g. NIH)
- Information made accessible to the public
- Investigator Training
Collaborative Science

• Relationship between Science and Industry, Academia, Government, and Society:
  • What research is to be funded and not funded
  • What research questions are deemed important
  • Restrictions on how research is practiced in the lab
  • The behavior of the researchers
Roles of the Scientist in Society

- There is a longstanding tension between the role of the scientist as "discoverer of how things work" and the expectations of many in society that scientists should "deliver tangible goods".
- Governments and societies have historically looked to scientists to explain natural laws, predict outcomes, and develop new technologies.
- In addition, governments often encourage scientists to advance specific national agendas, even though scientists are viewed by citizens as "independent authorities" able to represent "truths" that transcend national political purposes.
- Further, all new discoveries lead to changes in what can be applied, and hence the pursuit of discoveries does not take place without societal expectations.
- Therefore, many of these conflicts of interest affect the practice of science and the training of young scientists, as well as the environmental, ethical and societal impacts of scientific research.
Science and Society

Thinking about the relationship: expectations, effects, responsibilities

Does the scientist have a “special” or “recognized” role in society?

Who are these people and why do you know them?

Galileo

Pasteur

Mendel

Curie

They are cultural icons, remembered primarily for their discoveries of the *Laws of Nature* – discoveries in the realm of basic science.
Academic Interests vs. Business Interests

• Universities seek to educate students, to advance knowledge through research, and to conduct public service
• Business aims to maximize profits and to produce goods and services
• Non-profits also produce goods and services and seek financial growth and stability
Academic Interest vs. Business Interest

Higher learning institutions:
- Free exchange of data & ideas
- Academic freedom, free speech & free thought
- Honesty & objectivity in research
- Knowledge for its own sake
- Subsidized by government funds and have monopolistic control over local markets
- Ethical obligations to students, faculty, staff, alumni, community

Private corporations:
- Protect confidential and proprietary information
- Conduct research for specific purposes; may impose restrictions on public communication
- Honest & objective in principle, but also as a means of complying with law, enhancing market share, or ensuring product quality
- Utilization of knowledge for profit or other practical goals
- Compete in markets
- Legal obligations to stockholders, customers, employees, community
Activities Generally Not Allowed

• **Academic freedom restrictions**
  (such as prohibitions on publication by subordinates or evaluation of subordinates based on willingness to participate in activities that could benefit a business entity in which the superior has a significant financial or other interest)

• **Payments, incentives or gifts, directly or indirectly, from sponsors, to employees conducting human subjects research**
  (all funds must go into the restricted research account)

• **Solicitation or receipt of gifts**
  (in violation of the Utah Public Employees Ethics Act)
Acknowledgement

Presentation content includes class materials provided by several instructors in the Research Administration Training Training Series (RATS) at The University of Utah. Complete class descriptions and instructor information is available at

www.education.research.utah.edu
References

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• http://en.wikipedia.org/wiki/
• http://www.google.com/imghp?hl=en&q=cl&tab=vi
• http://www.youtube.com/
• http://www.niehs.nih.gov/research/resources/bioethics/timeline.cfm