



Tomorrow's Doctors, Tomorrow's Cures

Understanding, Identifying, and Managing Conflicts of Interest

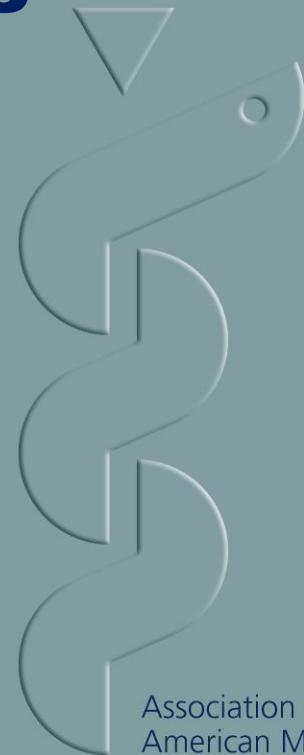
Learn

Serve

Lead

Heather H. Pierce, JD, MPH
Senior Director, Science Policy
Regulatory Counsel
hpierce@aamc.org

April 8, 2015
Howard University



Association of
American Medical Colleges

Goals for Today

- Define and describe conflicts of interest
- See how conflicts of interest can affect research
- Learn how conflicts of interest are identified and managed
- Understand the responsibilities of researchers, institutions, and the federal government
- Know which of your financial interests must be disclosed to your institution

True or False?

1. All conflicts of interest involve financial interests

Defining Conflicts of Interest

“A conflict of interest exists when two or more contradictory interests relate to an activity by an individual or an institution.” UCLA

"A conflict of interest in research exists when the individual has interests in the outcome of the research that may lead to a personal advantage and that might therefore, in actuality or appearance compromise the integrity of the research." NAS, Integrity in Scientific Research

“Situations in which financial or other personal considerations may compromise, or have the appearance of compromising, an investigator's judgment in conducting or reporting research.”
AAMC, 1990

“Conflicts of interest are circumstances that create a risk that professional judgments or actions regarding a **primary interest** will be unduly influenced by a **secondary interest**.”



*Conflict of Interest in Medical Research,
Education, and Practice*

Institute of Medicine, 2009

Primary Interests:

Promoting and protecting:

- The integrity of research
- The quality of medical education
- The welfare of patients

Secondary Interests:

Any other interests that may affect behavior

- Financial
- Personal relationships
- Academic or professional pressures

Mouse Vaccine Study

Antibody Detected



After the paper is published, you find out the following information:

- Dr. Russell has a consulting agreement with the company that will make the vaccine
- Dr. Russell sits on the hospital committee that will decide whether that vaccine will be administered to patients
- Dr. Russell owns stock in the company.
- Dr. Russell is hoping to be promoted.

Could these be seen as potential conflicts of interest?

True or False?

2. Every financial interest is a conflict of interest

Identifying Conflicts of Interest

- Potential conflicts of interest
- Perceived conflicts of interest
- Actual conflicts of interest

Identifying Conflicts of Interest in Research

- Financial relationships with companies who have a stake in the outcome of research (consulting, fiduciary roles, equity interests)
- Holding leadership positions in a company that makes a product related to research you do
- Receiving gifts from vendors or companies who have a stake in the outcome of research
- Involving students or trainees in research while having a financial interest in a company that could be affected by the research

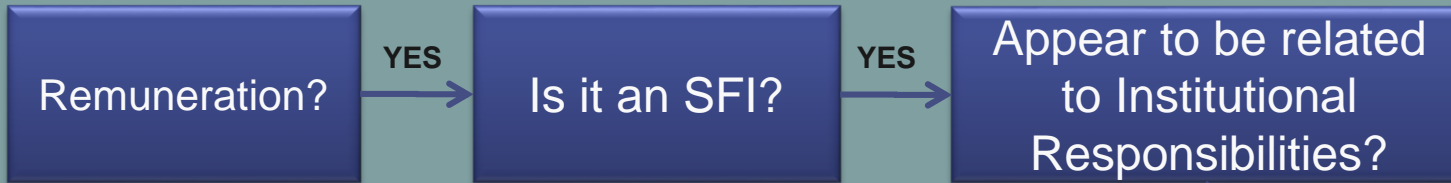
Key: A financial or other interest is somehow *related* to the research

True or False?

3. Federal law places obligations on both investigators and institutions to identify financial conflicts of interest

Public Health Service FCOI Regulations

Investigator Responsibilities



Institutional Responsibilities



SFI = Significant Financial Interest



* The SFI “could directly and significantly affect the design, conduct, or reporting of the PHS-funded research”

Disclosing Significant Financial Interests (Your Obligation)

Dr. Steinbeck has a grant from NIH to study the use of statins in patients who have had a coronary stent implanted.

- ✓ Dr. S. has a \$15,000 consulting agreement with Everstent.
- ✗ Dr. S. receives royalties through the school from the use of the first type of stent Everstent made.
- ✗ Dr. S. is on the hospital committee that decides which drugs to put on the formulary.
- ✓ Dr. S. is paid \$8000 by HealthPub to write textbook chapters on doctor-patient relationships
- ✓ Dr. S's husband owns stock in ProStent.
- ✗ Dr. S. is coming up for tenure in 18 months.

Determining If a Financial Conflict of Interest Exists

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Disclosed?



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(But may be prohibited by other policy)

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Who else cares about conflicts of interest?

- The Food and Drug Administration (FDA)
- The Centers for Medicare and Medicaid Services (CMS)
- Congress
- Institutional Review Boards
- Journal Editors
- Reporters
- Patients
- Research subjects

True or False?

4. Every conflict of interest can be managed

Managing Conflicts of Interest: Institutional Responsibilities

- When a conflict of interest is identified, an institution develops a **management plan**
- Elements might include:
 - Disclosure to patients, research subjects, students, academic audiences
 - Including a third party to conduct data analysis
 - Adding a second investigator to a project
 - Limiting the supervisory responsibilities of the conflicted researcher
 - Reducing the conflicting interest
- Conflicts of interest that cannot be managed must be eliminated

Managing Conflict of Interest: Researcher Responsibilities

- Researchers with identified conflict of interests must
 - Cooperate with the institution in developing, approving, and following the management plan
 - Ensuring that all elements of the management plan are followed
 - Notifying the institution if anything changes
 - Follow all other aspects of the conflict of interest policy, including training

True or False?

5. Management can be preferable to elimination of an identified financial conflict of interest



“A principled partnership between the academic community and industry is essential if we are to realize the promise of biomedical research”



“An effective and principled partnership between academic medical centers and various health industries is critical in order to realize fully the benefits of biomedical research and ensure continued advances in the prevention, diagnosis, and treatment of disease.”



Conflict of Interest in Medical Research, Education, and Practice

Institute of Medicine, 2009

“Patients and the public benefit when physicians and researchers collaborate with pharmaceutical, medical device, and biotechnology companies to develop products that benefit individual and public health.”

True or False?

6. Conflicts of interest represent a type of research misconduct

**Financial
Interest**



**Conflict
of Interest**

**Conflict
of Interest**



**Research
Misconduct**

Importance of Effective, Robust Conflict of Interest Policies

Maintaining integrity of research data
through identification of potential
sources of bias

Preserving public trust in research
process and results

Take Home Messages

1. Institutional policies that are strong, clear, and well enforced protect researchers, data integrity, resources, and the public trust
2. *We manage* potential conflicts when the underlying relationship is potentially beneficial
3. Ensuring that conflicts of interest do not undermine the efforts of the scientific community is a shared responsibility





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