Using Data to Inform Policies about Disclosing Financial Conflicts of Interest in Research

Jeremy Sugarman, MD, MPH, MA
Harvey M. Meyerhoff Professor of Bioethics & Medicine
Department of Medicine
Berman Institute of Bioethics
Johns Hopkins University
Baltimore, Maryland

Disclosure

I have/had bioethics advisory board or consulting relationships with Amgen, Genentech, and Merck Serono.

All of my COI-related research was sponsored by the National Institutes of Health

Objectives

• To discuss the nature of financial conflicts of interests in research
• To review data related to the disclosure of financial interests to potential research participants
• To describe how such data can inform policies and practices regarding disclosure

A Patient

• 18 yo with diet-controlled OTC-deficiency
• Enrolled in a Phase I gene transfer experiment at the University of Pennsylvania
• Transfected with adenovirus vector via hepatic injection
• Developed hepatic failure and died
Spectrum of Conflicts

- Initial considerations
- Research design
- Prospective review
- In process
  - Recruitment
  - Informed consent
  - Integrity of the data
- Reporting

Selected Types of Financial Interests

- Per capita payments
- Money received outside the study
- Investigator holds equity
- Institution holds equity

Potential Solutions

- Divest
- Minimize
- Disclose

“Please be aware that the University of Whentenwhistle, Dr. Joyce K. Hanson (the Director of the Center for Human Genome Study), and Acme, Inc. (a bioetchnology company in which Dr. Hanson holds an interest) have a financial interest in a successful outcome from the research involved in this study.”
Important Empirical Questions Regarding Disclosures of COI

- Who, What, When, Where, and How?
- How will these data be used?
- What are the effects on trust?
- What are the effects on the research enterprise?

Overview

- Overview of COINS studies
- Potential goals of disclosure
- Recommendations

COINS Overview

- Review COI Policies
- Obtain Stakeholder Input
- Develop Model Disclosures
- Evaluate Effects of Disclosure

Conflict of Interest Notifications Study

- Duke
  - Jennifer Allsbrook
  - Joëlle Friedman
  - Alice Fortune-Greeley
  - Chantelle Hardy
  - Li Lin
  - Kevin Schulman
  - Kevin Weinfurt

- Johns Hopkins
  - Jeremy Sugarman

- Wake Forest
  - Mark Hall
  - Nancy King
  - Jan Lawlor

NHLBI Grant: 1 R01 HL075538-01
COINS Overview

Review COI Policies → Obtain Stakeholder Input → Develop Model Disclosures → Evaluate Effects of Disclosure

Potential Participants
IRB Chairs
COIC Chairs
Investigators
Research Coordinators


COINS Overview

1. Promote informed decision making

Overview

- Overview of COINS studies
- Potential goals of disclosure
- Recommendations

Challenges

- Differing views on what should be disclosed
- People have trouble understanding
- Can exacerbate therapeutic misconception
- Study coordinators often lack information
- Artificially increasing salience of financial disclosure?
2. Honor Participants’ Perceived Right to Know

- Disclosures make a difference to some people, especially of equity relationships.
- Disclosures do not affect most people.
- People still want to know

What is material to the decision?

3. Establish or Maintain Trust

- Disclosure could increase trust
- Disclosure can decrease trust
  - Especially for equity relationships
- Overall, most disclosures do not undermine trust
4. Minimize Legal Risk for Research Institution/Investigator

- In some states, no liability risk for failing to disclose
- No precedent for a disclosure being sufficiently thorough

“Please be aware that the University of Whentenwhistle, Dr. Joyce K. Hanson (the Director of the Center for Human Genome Study), and Acme, Inc. (a biotechnology company in which Dr. Hanson holds an interest) have a financial interest in a successful outcome from the research involved in this study.”

“Please be aware that the University of Pennsylvania, Dr. James M. Wilson (the Director of the Institute for Human Genome Therapy), and Genovo, Inc. (a gene therapy company in which Dr. Wilson holds an interest) have a financial interest in a successful outcome from the research involved in this study.”
5. Deter Troubling Financial Relationships

• Assumes investigators dislike disclosing.
  • No data to support this.
  • Others usually do the disclosing.
• Could create moral license (caveat emptor)

6. Protect Research Participants’ Welfare
• No systematic evidence to suggest harm
• Any protection would have to result from . . .
  • improving informed decision making
  • deterring investigators from dangerous financial relationships

Overview

- Overview of COINS studies
- Potential goals of disclosure
- Recommendations

1. Participants should not be sole decision makers about risks of financial relationships.
2. Disclosures should be brief and simple, with opportunity to ask questions.
3. Equity relationships should be discouraged, not simply disclosed.
4. Study personnel should receive training they need.
5. Be explicit about goals of disclosure.