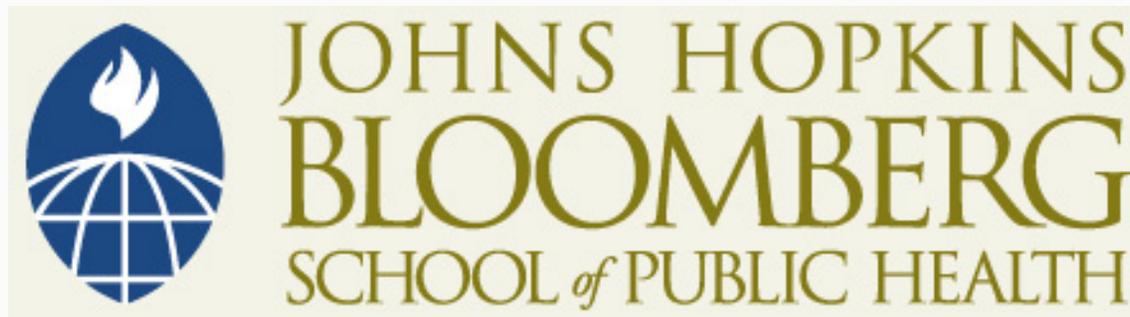


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## Section B

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Mechanisms to Address COI: Individual Level

# Guidance from the Regulations, I

- ICMR—calls for full disclosure of COI and withdrawal from the decision-making process in IECs
- NCESSRH—COI in peer review processes
- CIOMS—similar to ICMR
- Need for institutions to self-regulate to monitor, prevent, and resolve COI

# Guidance from the Regulations, II

- CIOMS-epi
  - Researchers are not to have undisclosed COI with sponsors or subjects
  - Researchers are not to be employed in any of the interest groups and therefore subject to pressure to distort study findings
  - Review processes must not tolerate COI; or request disclosure

# COI: Individual

- In informed consent forms
  - Include the researcher's sources of funds
  - Researcher's affiliations
- Blinding of study, when possible
- Outside DSMB or other monitoring
- Forbid review of colleagues' work
- Peer review of manuscripts
- Avoid contracts requiring prolonged prepublication review or interfering with investigator's access to data

# COI: Individual

- Review processes
  - Journals now ask for COI statements to be filed, often from both authors as well as reviewers
  - Journals ask for sources of funds to be mentioned as well

# Conflict of Interest and Publishing

- *New Engl J of Med*
  - One of the first major journals to develop policy
  - Authors must disclose “financial connections with industry”
  - Authors of editorials or review articles prohibited from “any financial connection with a company that benefits from a drug or device discussed” in the article (disclosure not sufficient)
- *Lancet*—current guidelines
  - “. . . must disclose any financial and personal relationships with other people or organizations that could inappropriately influence (bias) their work
  - Examples of financial conflicts include “employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications, and travel grants, all within three years of beginning the work submitted”
  - “Investigators should disclose potential conflicts to study participants and should state in the manuscript whether they have done so.”

# Conflict of Interest and Publishing

## ■ *BMJ*

- Set of four questions to see if competing financial interests exist (“We will not reject papers simply because you have a competing interest, but we will make a declaration on whether or not you have competing interests”)
- Also asks if you want to disclose any other competing interests (close relationship or antipathy to person, academic link or rivalry, membership in a political party or special interest group, or deep personal or religious conviction)
- Asks these of the reviewers as well

- “Conflicts of interest are ubiquitous and inevitable in academic life, indeed, in all professional life. The challenge of academic medicine is not to eradicate them, which is fanciful and would be inimical to public policy goals, but to recognize and manage them sensibly and effectively.” (Korn, *JAMA*, 2000)



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## Mechanism of Redress: Institutional

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# Guidance from the Association of American Universities

- In cases of institutional COI
  - Disclose
  - Manage COI in most cases
  - Prohibit concerned activity when necessary

# Institutional COI: Redressal Mechanisms

- COI committee with participation from a range of external members who have no stake in the outcome of the research
- Set up the IEC in a manner so that its positioning within the administrative setting ensures independent review

# Example

- You are Mr. X, a doctor in a busy urban nursing home. You have a lot of patients who have been faithfully coming to you as their family physician. A drug company is interested in doing research (drug trial) on the diabetics in the urban population. They offer you Rs 7500 for every patient enrolled in the clinical trial, as well as a fully paid family vacation to Mauritius when you complete enrolling 25 patients into the trial.
- Questions
  - Is there a conflict of interest?
  - How can the situation be handled?
  - Should the research still take place?

# Summary

- Definition of COI
- Need to recognize it
- Types of COI
- Models and mechanisms to address COI

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