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Conflicts of Interest

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Ethical Social and Cultural Program for the Grand
Challenges in Global Health Initiative

Objective of Session

- Identify types of conflicts of interest, at what level of research these can occur, their potential consequences, and methods to minimize their occurrence

Points to Be Covered

- What is conflict of interest?
- Why is it important?
- Types of conflict of interest
- How can it be addressed?



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Section A

Definition Overview

Definition of Conflict of Interest (COI)

- A conflict of interest is a set of conditions in which professional judgment concerning a primary interest (such as a patient's welfare or the validity of the research) tends to be unduly influenced by a secondary interest (such as financial gain)
 - Thompson, D. F. (1993, August 19). Understanding financial conflicts of interest. *N Engl J Med*, 329, 8, 573-576.

COI

- Not a behavior of an individual or institution but a condition that prevails

COI

- Many kinds of conflicts of interest, at all levels of research
- Some obvious, many more subtle
- Can usually avoid, or at least minimize
- Requires thought and knowledge beforehand

Clinical Research

- Increasing amount of funding from pharmaceutical companies (as compared to earlier when it came more from governments)
- 70% of money for clinical drug trials in the U.S. comes from industry (Bodenheimer, *N Engl J Med*, 2000)
- Growing number of CROs in India
- Pressure to report positive findings because of business interests

Major Impetus for Industry/University Collaboration

- Lead to concern regarding influence of industry in academic centers, both at the individual and institutional level

Relevance of COI to Research Enterprise

- Potential for the conflict of interest to produce different results
- Sources of funding for academic research—public to private sources
- Risk of erosion of public trust

Why Do We Address COI?

- To minimize the influence of secondary interests, such as personal financial gain, that should be irrelevant to the merits of decisions about primary interests, such as the care of patient, conduct of research or review
- The second is to maintain confidence in professional judgment

COI: Levels

- Individual
- Institutional

Types of Conflict of Interest—Individual

- Financial interests in outcome
- Working on similar topic and has an interest in outcome (positive or negative)
- Ideological position that views the study negatively/positively that biases decisions
- Is not working but has an interest in the research being undertaken (such as head of the department where P.I. works, etc.)

Types of Conflict of Interest—Individual

- Financial interests in outcome
- Working on similar topic and has an interest in outcome (positive or negative)
- Ideological position that views the study negatively/positively that biases decisions
- Is not working but has an interest in the research being undertaken (such as head of the department where P.I. works, etc.)

COI: Individual

- “Other sources of conflict are personal, political, academic, and religious and we believe that those may be just as potent as financial conflicts”
 - Smith, R. (1994, January 1). Conflict of interest and the BMJ. *BMJ*, 308, 6920, 4-5.

Implications for Research

- Affects
 - Consent process
 - Review processes

COI: Consent Process

- Information provision
 - The person taking the informed consent has a vested interest in completing the research and not only the subject/participant
- Possible solution—consent to participate in the research is obtained through independent persons not directly affiliated to the research

COI: Review Processes

- Peer reviewing—individual affiliations and interests
 - Similar work in progress
 - Personal affiliations, etc.
 - Financial or other stake holding
- IEC processes
 - Financial COI
 - Other issues similar to individual COI

COI: Institutional (def.)

- When any of an institution's senior management or trustees or a department, school, or subunit or an affiliated foundation or organization has an external relationship or financial interest in a company and that company itself has a financial interest in a faculty research project

Other Institutional COIs

- Ethics committees themselves may be subject to institutional pressures to approve research activities in which the institution has a financial stake
- Institutional stake in grant coming to institution
- Extreme case—corruption, for example, bribing authorities for approval

Models of Managing COI

- Prohibition, that believes that any relationship presents a COI
- Disclosure and peer review (believes that COI are unavoidable and financial interests are the least scientifically dangerous)