

Conflicts of Interest in Clinical Research

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Why worry about COIs?

Randomized, placebo controlled Phase II study
of an investigational drug conducted by a
large, publically traded drug company

Consider the following scenarios:

- ▶ PI owns stock worth about \$10,000
- ▶ PI owns stock with about \$250,000
- ▶ PI is on an advisory Board for the
pharmaceutical company, receives \$50,000
plus \$100,000 for his services

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Why worry about COIs?

Clinical trial of an investigational device

Consider the following scenarios:

- ▶ PI is licensed by the University to the company & she receives royalty income.
- ▶ PI founded and owns the small company that is seeking approval of the device.
- ▶ PI is on the faculty of the University. The University is receiving grants from the sponsor. The PI will be given the right to publish the findings of the research.

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Why worry about COIs?

- ▶ COIs can cause investigators and other parties to make biased decisions that are not in the subject's best interest.
- ▶ The role of the IRB in reviewing COIs is to determine whether a COI may create bias, and if so, whether or how the COI can be controlled.

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Types of Financial Conflicts of Interest

- ▶ Equity interests, including stock options or warrants
- ▶ Consulting Fees
- ▶ Speaking Fees
- ▶ Corporate Officer or seat on Board of Directors
- ▶ Career Advancement
- ▶ Other employment relationships

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Parties Who Can Have Conflicts of Interest

- ▶ Investigator
- ▶ Sub-investigator
- ▶ Other research staff (coordinator, etc.)
- ▶ Family member
- ▶ Institution (Hospital, clinic, etc.)
- ▶ IRB members

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Analyzing a COI

- ▶ Possible affect of the COI on subjective decision making (very difficult to determine).
- ▶ Subjective decisions that could be influenced by a conflict include the design of the research, choosing which subjects to enroll, clinical care provided to the subjects, use of subjects' confidential medical information, data collection and analysis, adverse event reporting, and the presentation of research findings.

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Analyzing a COI

- ▶ Amount of risk to subjects.
- ▶ Amount of interaction between the conflicted party and the subjects.
- ▶ Other oversight of the conflict of interest; COI committee, institution, government, etc.
- ▶ What is the nature of the conflict, and how closely related is it to the research?
- ▶ Is the investigator uniquely qualified to conduct the research?

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Reasonable Person Standard 1

- ▶ Would the financial conflict of interest challenge the integrity of a reasonable individual?

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Reasonable Person Standard 2

- ▶ Would the financial conflict of interest appear to a reasonable member of the general public to be a conflict that could challenge the integrity of the conflicted party?

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Value of using a Reasonable Person Standard

- ▶ By using a reasonable person standard, the IRB moves away from questioning the integrity of the investigator.
- ▶ This makes IRB action seem less personal.

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Managing a COI

Three Basic Approaches to a Conflict:

- ▶ No action necessary
- ▶ Some control necessary
- ▶ Controls not sufficient, the conflicted party cannot participate in the research

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Managing a COI

Disclosure

- ▶ Very common approach.
- ▶ Simple to implement, for example, put investigator's conflict in consent form.
- ▶ Criticisms of Disclosure: Puts the burden on the subjects, and subjects do not have sufficient knowledge to interpret.

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Managing a COI

Other controls

- ▶ Conflicted party cannot participate in consent process.
- ▶ Conflicted party cannot analyze data for publication.
- ▶ Conflicted party cannot determine eligibility.
- ▶ Conflicted party cannot monitor adverse events for safety.

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Managing a COI

Other controls

- ▶ Conflicted party cannot be the principal investigator.
- ▶ Additional oversight such as outside monitor, more frequent IRB review.