

Protecting people who participate in research

*CITI Training Study Guide
Conflicts of Interest*

What is a Conflict of Interest?

- Conflicts between a researcher's personal or financial interests, and the interests of a participant, patient or client.
- Competing loyalties, for example between a subject/client/patient and a research sponsor, employer or insurance company.

Conflict of Interest - Obligations

DHHS requires that researchers disclose to institutional officials (e.g., MSU, FPCC) any "significant financial interest" that could affect the design, conduct or reporting of research.

- It's a conflict of interest if the "interests" are reasonably related to the researcher's institutional responsibilities.
- Institutional officials must "manage" the conflict to prevent misconduct.

Conflict of Interest - Obligations

FDA has different definitions for clinical investigators. It's a conflict of interest if...

- compensation to the investigator could be affected by a study's outcomes.
- the investigator has a proprietary interest in a product being tested
- the investigator has an equity interest in the sponsor of a study with undetermined value
- the investigator has an equity interest in a publicly held company that exceeds \$50,000.
- the investigator is paid \$25,000 or more by a study sponsor

**Significant Financial Interest –
DHHS Legal Definition**

- Payment from, or equity interest in, a “publicly traded entity” that exceeds \$5,000.
- Payment from a “non-publicly traded entity” that exceeds \$5,000, or any equity interest in that entity.
- Patents or Copyrights that are generating income.
- Disclosure is also required for travel sponsored by a private entity, paid expert testimony, consultancy, speakers' fees, or gifts.

What does not have to be disclosed?

- Investments (e.g. retirement accounts) where someone else makes the investment decisions
- Income from seminars, lectures, or service to a government agency, academic institution, or hospital

How does an institution manage conflicts of interest?

- Institutions must make conflict of interest information available to the public, upon request
- Investigators must complete a conflict of interest training
- Institutions must designate an official to solicit and review the disclosures
- Researchers must submit updated disclosures at least annually

What should an IRB ask about conflicts of interest?

- How is the research supported or financed?
- Where and by whom was the study designed?
- Do individuals or institutions receive compensation that may be affected by the study's outcomes?
- Could financial relationships and interests negatively affect the rights and welfare of subjects?
- Would taking additional measures better protect subjects' rights and welfare?

What could an IRB recommend to reduce or manage conflicts of interest?

- Peer review of the study design
- Independent oversight of the research
- Have an investigator with conflicts of interest abstain from problematic aspects of the study
- Disclosure of financial interests to subjects on the consent form.
- Reporting of investigator's financial relations or conflicts of interests in all presentations and publications associated with the research
