

Two Offices Divided by a Common Goal: CoI and IRB Review

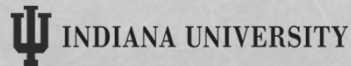
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Learning Objectives

- ◆ Identify points of overlap and divergence in the COI and IRB processes
- ◆ Understand best practices for COI and IRB review of outside financial interests related to human subjects research.

The Regulations

- ◆ What do Human Subject Research Regulations say about Conflict of Interest?
- ◆ What do Conflict of Interest Regulations say about Human Subjects Research Protections?

The Regulations

- ◆ HSR Regulations
 - ◆ PHS: CFR 45 Part 46. Protection of Human Subjects: 1991? 2018?
 - ◆ FDA: CFR 21 Part 50. Protection of Human Subjects
 - ◆ Focus
 - ◆ To review and approve participation of subjects of HSR
 - ◆ And no mention of conflict of interest

The Regulations

- ◆ CoI Regulations
 - ◆ PHS: CFR 42 Part 50 Subpart F. Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is sought
 - ◆ FDA: CFR 21 Part 54. Financial Disclosure by Clinical Investigators
 - ◆ Focus
 - ◆ Review financial interests related to research that might effect design, conduct and reporting of research
 - ◆ To protect objectivity of research
 - ◆ And no mention of protecting human subjects

The Regulations

- ◆ So.....
 - ◆ Is conflict of interest a human subject protection issue?

In Practice

- ◆ Notwithstanding lack of regulatory requirement, for a very long time HSR reviewers have been asking about CoI
 - ◆ Under risk/benefit
 - ◆ Under qualifications of researcher/research team
- ◆ Institutionalized by AAHRPP
 - ◆ Organization has and follows written policies/procedures to ensure that research is conducted so that financial CoIs are identified, managed and minimized or eliminated
 - ◆ I.6.A. ... to identify, manage, and minimize or eliminate financial CoIs of the Organization
 - ◆ I.6.B. ... to identify, manage, and minimize or eliminate financial CoIs of researchers

The Process

- ◆ Researchers Disclose Financial Interests
 - ◆ Who discloses?
 - ◆ All researchers? Key personnel?
 - ◆ Include interests of spouse and dependent child(ren)
 - ◆ Domestic partner? Non-dependent child(ren)? Siblings?
 - ◆ What financial interests?
 - ◆ PHS says significant financial interests (SFI): >\$5,000

The Process

- ◆ "Someone" needs to Review and Assess SFI
 - ◆ Accept disclosures of significant financial (SFI) interests related to research
 - ◆ Determine if SFI constitutes a financial conflict of interest
 - ◆ PHS: Could the financial interest directly and significantly effect the design, conduct and reporting of research?
 - ◆ Who is this someone?
 - ◆ CoI Committee?
 - ◆ CoI Official?
 - ◆ IRB?

The Process

- ◆ "Someone" Needs to Take Action
 - ◆ To develop management plan to eliminate, minimize, manage the CoI
 - ◆ Who?
 - ◆ How?
 - ◆ Disclosure
 - ◆ Modification of research plan
 - ◆ Restricted from conducting parts of the research
 - ◆ Required to obtain independent monitor
 - ◆ Required to either eliminate interest or not conduct research
 - ◆ To ensure IRB/IRB reviewer has access to management plan to accept and/or add to if not performed by IRB
 - ◆ To enforce and monitor adherence to management plan

Beyond Regulations

- ◆ Institutional/Organizational Conflict of Interest
 - ◆ No Federal requirement to review of Institutional CoI
 - ◆ But AAHRPP requirement
 - ◆ AAMC, AAU, etc recommendation
 - ◆ Thus, often ICoI relates only to human subject research
 - ◆ Conflicts of interest based on either the financial interests of the institution itself or of its officials acting in leadership or supervisory positions, are of special concern in the conduct of human subjects research. (AAMC)

Beyond Regulations

- ◆ Institutional/Organizational Conflict of Interest
 - ◆ An institutional financial conflict of interest may occur when the institution, any of its senior management or trustees, or a department, school, or other sub-unit, or an affiliated foundation or organization, has an external relationship or financial interest in a company that itself has a financial interest in a faculty research project.(AAU)
 - ◆ In addition to financial interests of the Hospital's leadership, institutional conflicts of interest include situations in which the financial investments or holdings of the Hospital, gifts to the Hospital (including restricted or unrestricted monetary gifts), or other financial interests of the Hospital might affect or reasonably appear to affect institutional processes for the design, conduct, reporting, review or oversight of human subjects or other research. (CHOP)

Beyond Regulations

- ◆ Institutional/Organizational Conflict of Interest
 - ◆ Specifically relevant to:
 - ◆ Intellectual Property (IP)
 - ◆ Institutional Investments
 - ◆ Gifts
 - ◆ Financial interests of Senior Administrative Officials
 - ◆ Same process
 - ◆ Disclosure
 - ◆ Review/Assess
 - ◆ Take action
 - ◆ But with differences due to 'institutional'/'organizational' nature of the conflict

Beyond Regulations

- ◆ Unique Questions for I-CoI
 - ◆ Can an institutional committee review a institutional conflict?
 - ◆ At what level?
 - ◆ Some institutions, I-CoI Committee distinct from CoI Committee
 - ◆ Some institutions, send human subjects research involving I-CoI to independent IRB
 - ◆ Remember, no formal requirement to act as per PHS or FDA regulations

Thank You

- ◆ Questions and Comments