Confronting Conflicts: Identifying and Managing Conflicts of Interest in Research

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Introduction

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Introduction

- **Aims of Session**
  - Identify and discuss the challenges in fulfilling responsibilities related to conflict of interest in research
  - Identify and discuss practices for monitoring compliance with conflicts of interest management plans

- **In Broadest Sense: A Conflict**
  - Any situation in which financial, professional, or personal obligations may compromise or present the appearance of compromising an individual’s or group’s professional judgment in conducting, reviewing, or reporting research

- **Ours a bit narrower**
Regulatory Context

- PHS: CFR 42 Part 50 Subpart F. Promoting Objectivity in Research
  - [https://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=992817854207767214895b1fa023755d&rgn=div5&view=text&node=42:1.0.1.4.23&idno=42#sp42.1.50.f](https://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=992817854207767214895b1fa023755d&rgn=div5&view=text&node=42:1.0.1.4.23&idno=42#sp42.1.50.f)

- The North Star…..
  - Standard upon which most institutions frame their program regardless of federal funding
Regulatory Context

- Briefly, requires:
  - Policy
  - Designate responsible official (s)
  - Disclosure
  - Assessment of disclosure if conflict or not
  - If conflict, development of management plan to
    - Eliminate, reduce, manage what remains

- Note
  - Covers individual conflicts of interest
  - No reference to institutional/organizational conflicts of interest
  - No reference to conflict of commitment
"With the money we'll save by shutting down quality control, we can issue some truly spectacular apologies."
Process

- Disclosure
  - Who?
    - Financial interests of researcher(s)
    - Including spouse and dependent children
  - What?
    - All(any) Financial Interests?
    - All Significant Financial Interests?
      - PHS: $5,000
      - FDA: Varies by type of interest (50K, 25K)
    - At your institution?
Process

Disclosure
- When?
  - At least annually
  - When changes

Assessment
- By Whom
  - CoI Official?
  - CoI Committee?
  - Your institution?
Process

- **Assessment**
  - Could the financial interest *directly and significantly* effect the design, conduct and reporting of research
  - We usually ask this with eye towards ‘positive’ association between researcher and characteristics of research
    - Sponsor, product that is subject of research, etc
    - But, what about ‘negative’ association
      - Competitor product?
Process

- Assessment
  - Make Determination
    - If not directly and significantly ........
      - Then what?
    - If directly and significantly
      - Develop management plan
Process

- Develop Management Plan
  - Designed to
    - Eliminate
    - Reduce what can’t be eliminated
    - Manage what remains
Process

- Develop Management Plan
  - Common elements of management plan
    - Public disclosure of financial interests
    - Monitoring/external review of research or portions of research by independent reviewer(s)
    - Modification of research plan
    - Disqualification from participating in all or portion of research
      - Recruiting; initial data analysis
      - Severance of relationship that creates the conflict
Process

- Monitor Adherence to Management Plan
  - Disclosures in publications
  - Audit studies to confirm other elements of plan followed
- If you don’t……
Why? To minimize not knowing what’s around the corner.

"Wait until one of them says, ‘It’s so peaceful out here.’"
Next Steps

- From Research Administration Perspective
  - Reporting to funding source
  - That is about it

- From Human Subjects Protection Perspective – More to Come
CoI and Human Subject Protections

- CoI Regulation
  - No mention of human subject protections whatsoever

- HSR Regulations
  - 45CFR46: Common Rule
  - No mention of CoI whatsoever

- So How Did They Come Together/Overlap?
  - In practice
CoI and Human Subject Protections

- **Informal: Criteria of Approval**
  - Risks are minimized
  - Qualifications of researchers
  - Financial interests might impact minimization of risk
- **Risk-Benefit**
  - Financial interests might impact presentation of risks and benefits
- **Selection of subjects**
  - Financial interests might skew selection of subjects
CoI and Human Subject Protections

- **Formal:** Institutionalized by AAHRPP
  - **Standard I-6.**
    - 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 that could influence the conduct of the research or integrity of HRPP
    - I.6.B. … to identify, manage, and minimize or eliminate financial CoIs of researchers and research staff that could influence the conduct of the research or integrity of HRPP.
CoI and Human Subject Protections

- CoI Management Plan to IRB
  - IRB has final review/approval
  - IRB has authority to
    - Accept management plan
    - Add to management plan
Individual CoI

**Annual Disclosure**
- If no related to any identified research: Process stops
- If disclosed as related:
  - To CoI Committee
  - Management plan is created and given to IRB

**IRB Protocol**
- If financial interest is identified:
  - Staff collects and reviews management plan, or other CoI Committee
  - CoI outcome (management plan or other) is presented to IRB for review and acceptance as is or additional restrictions are added
- If no financial interest on annual CoI disclosure and no financial interest on IRB’s CoI questions:
  - Process is complete
Wrap-Up

- Questions?
- At Your Institution?