Conflict of Interest in the Execution of Research

Cordell M. Overby, Sc.D.
Associate Provost for Research

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Session Objectives

• What is conflict of interest?
• What are some common ways that it presents itself?
• Things you should know.
Session Purpose

• To familiarize audience with central tenets of “potential” conflict of interest in the research arena
Concern ... if potential is realized

- Conflict of interest refers to situations in which financial or other personal considerations may compromise, or have the appearance of compromising, an employee’s professional judgment with regard to the research they are conducting.
Concern … if potential is realized (continued)

• Under 42 CFR Part 50, institutions must certify that they maintain a “written, enforced policy” on conflicting interests. Institutions must also report the existence of any conflicting interests and assure the interests have been “managed, reduced or eliminated.”
Potential for “Conflict”

- Is not inherently bad … so, disclose
- If conflict actually develops … must be managed
- Management plans must be periodically reviewed
“Conflict” Guidelines

• From institutions
• From states
• From federal agencies
• To assure
  – Research integrity
  – Fiscal responsibility
University of Delaware has ...

- “Conflict” of interest policy
- “Conflict” process
- Based in case specifics & detail
- Web based disclosure
UD Policy Provides for …

• Disclosure of
  – Consulting agreements
  – Substantial ownership
  – Participation
    • In entity that supports employee’s UD function
    • In key role for commercial entity
    • In commercial entity on day-to-day basis
UD Policy Provides for … (continued)

- Disclosure of
  - Participation (continued)
    - In development & transfer of UD know-how to commercial entities
  - Situations with potential or perception of conflict
UD Policy Provides for … (continued)

• Specifics to be included in disclosures
  – Nature of relationships
  – Period of relationships (short vs. long term)
  – Entity name
  – Benefits to UD, entity & employee
  – % of employee’s time
  – How to avoid conflict w/ UD obligations
UD Conflict of Interest Process

• Primary players
  – Faculty &/or professional staff
  – Unit head
  – Dean
  – Dean’s College Conflict Advisor Committee
  – Provost
  – Provost’s University Conflict Committee
UD Conflict of Interest Process (continued)

• Disclosure of “interest” to unit head
• Informally resolve matter w/ unit head
• If unresolved, unit head submits to dean’s advisory committee
• If dean’s resolution unacceptable, refer to provost & university conflict committee
UD Conflict of Interest Process (continued)

• Provost makes final determination
• Faculty/Professional Staff
  – Maintains file
  – Reports status changes
• Biannual administrative review or upon substantial change
Financial Conflicts May Lead to Conflicts in …

- Commitment
- Conducting research
- Protecting research subjects
- Use of institutional resources
Conflict of Commitment

- Research responsibilities
- Teaching responsibilities
- Clinical responsibilities
- Administrative responsibilities
- Community service responsibilities
Conflict in Conducting Research

- Bias in design of research
- Bias in conduction & analysis of research
- Bias in reporting research
Conflict in Protecting Research Subjects

- Inappropriate enrollment of subjects
- Flawed informed consent
- Inadequate patient care
- Inadequate reporting & management of adverse events
Conflict in Use of Institutional Resources

- Non-UD research conducted in UD facilities
- Non-UD research conducted by UD persons
- Non-UD research conducted with UD equipment
- UD research resources provided to non-UD entity
Presentation Resources

- Huron Consulting Group
- University of Delaware Policy 6-11
- UTSA Research Integrity & Compliance
- 42 CFR Part 50
Questions

• Unit head
• overbyc@udel.edu or (302) 831-2383