Conflicts of Interest (COI’s): Vulnerabilities Associated with Complex Career Endeavors.

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Aims & Talking points

- Research 101
  - Controlling for Bias; Striving for Objectivity

- Subtleties of Bias

- Real vs. Perceivable Bias
  - Conflicts of Interest (Management)
  - People with Complex Careers

- Scandal vs. Wrongdoing
  - “I’m not doing anything wrong.”
Historical Model – Type 1. The university hires faculty that apply for federal research $$\text{.}$$ The grant gets funded, which benefits the faculty career and supports the institution. Faculty make discoveries that are published/shared or they sit on laboratory shelves.
Type 2. University hires faculty that coordinates with industry for research support. Industry sponsors faculty research which benefits faculty careers and supports the institutions. Faculty make (publishable) discoveries that are owned by the corporation.
The Bayh-Dole Act sought to get discovery out of the literature and off the laboratory shelves so that it could be applied to serve the people (tax payer).
Faculty made the discovery and deserve to reap the rewards of ingenuity & sweat. Public paid for discovery and thus discovery should be rapidly made available to public.
Scandals that Can Arise

- Media
- Jealous colleagues – Success breeds jealousy
- Institutional Conflict of Commitment
  - Managing Institutional Commitments vs. Private Commitments
- Student/Colleague involvement in discovery
  - Intellectual property & contributions
- Federal Regulations
  - Keeping finances/resources separate
  - Appropriate flow of information
Disclosure of Significant Business or Financial Interests that may Represent Conflicts of Interest

Key Point: Conflicts of Interest related to Sponsored Projects
- Must have Sponsored Research
- Faculty private enterprise must be perceivably related to sponsored project
The IFDC – Investigator Financial Disclosure Committee

- Faculty Committee
- Review and modify OP 74.17
- Not directly involved in managing conflicts related to OP10.20 nor Regent’s Rules
  - These policies/rules still apply
  - OP 10.20 – Conflict of Interest and Commitment policy
  - Conflicts of Interest between TTU responsibilities & private enterprise
- Review and modify Financial Disclosure System
- Review Positive Disclosures to assess need for management
- Created “standard” management plan
- Provide guidance on managing unique conflicts of interest
Where is the Ethical Dilemma?

- Externally Funded Research
- Disclosure of Financial Interests
- Financial Conflict of Interest?
- Research Activities
Historical Truth
Faculty have always had Conflicting Priorities
Where is the Ethical Dilemma?

Answer:
(1) Choice of financial interests & activities.
(2) Disclosure of interests & activities that a "reasonable person" would conclude is a problem.
Please answer the following regarding your business or financial interests (currently or for the next 12 months) that would reasonably appear to be affected by the research or educational activities funded, or proposed for funding, by an external sponsor.

- Remuneration (e.g., consultant compensation) that you and/or your family members would receive in excess of $5,000 from a single external entity
- Equity interest in excess of $5,000 value from a single external entity.
Financial Disclosures Rely on Ethics (honest answers).

- Explain how your financial and/or business interest in the entity could benefit from the sponsored project(s) on which you serve as principal investigator, co-investigator or senior personnel.
What is “Managed”?

Goals of Management Plans

- Transparency
- Separation of Sponsored projects and private faculty enterprise
- Flow of Information
- Protection of Students/Subordinates and Mentors/managers
- Customized Items for unique challenges
Financial Conflicts of Interest are not “bad”; They simply need to be managed.

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Protecting Your Reputation!!

- Step 1. Transparency elicits Trust; Secrecy elicits suspicion
- Step 2. Request/Construct a Management Plan with FCOI
  - Communicate with Committee & Personnel
- Step 3. Comply with Management Plan
- Step 4. Keep Accurate Records (i.e., personnel, data, contracts, communication) as required by management plan
NEW PUZZLE
The model becomes much more complex for industrious faculty. Faculty are hired by an institution and they may be conducting both federal and privately funded research which benefits both the faculty career and the institution. Discoveries made by faculty can lead to small companies that are owned in partnership by both faculty and the university (because institutions are part owners of intellectual property developed at the university with federal dollars). The university/faculty partnership create a company that applies for an SBIR/STTR grant. The company then contracts back to the university/faculty so that the university/faculty conduct research associated with the SBIR/STTR grant. So now, all parties are vested in the outcome of the research because they are joint owners of marketable research. Thus, all parties are conflicted.

Wow!!! How do we avoid Scandal Now?!
Potential Problems

- Researchers are Full-time employees of the University
  - Researchers are not businessmen (CEOs)
  - Working on SBIR/STTR (small business grants) on TTU time?
  - Ownership of companies while working at TTU?
  - Separating federally sponsored research from R&D for private enterprise?
    - Appropriate Flow of Information

- Universities are not Corporations
  - Faculty are not paid to run businesses – Building a business AND fulfilling TTU duties
  - Students are not employees – TTU does not provide salary/benefits to students/postdocs working as business employees – Protecting Students

- Potential for Profit = Potential for Bias

• Many unanswered questions.
• Rapidly evolving federal regulations.
• Rapidly Evolving ethics.