Financial Conflicts of Interest

Welcoming remarks will begin at 11:55 a.m. Eastern Daylight Time.

The formal presentation will begin at noon.

Sponsored by:

University of Pittsburgh
Office of Technology Management
Financial Conflicts of Interest

Presented by:
Susan Ehringhaus
Association of American Medical Colleges
Chris McKinney
Vanderbilt University
Dave Richardson
Penn State University

Questions?

We will be taking questions during two question and answer periods, one at the conclusion of the case studies and the other at the conclusion of the presentation.
Operator Assistance

Audio difficulties: Dial "* 0"

Other issues: + 1-847-559-0846

Remember to complete your survey after the event!

Thank You.
Dave Richardson
Pennsylvania State University

Financial Conflicts of Interest
“A webinar for advanced and experienced licensing personnel”

Susan Ehringhaus
Association of American Medical Colleges

Chris McKinney
Vanderbilt University

Dave Richardson
Pennsylvania State University

August 19, 2009
Workshop Description

Researchers at universities have unique opportunities to advance technology while establishing relationships with business entities that have an interest in commercializing technology. However, a significant financial conflict of interest may arise from such situations for researchers and their institutions. Congress is paying more attention to these conflict of interest issues, and universities can expect more detailed reporting of conflicts of interest to government sponsors, as well as the implementation of enhanced internal financial conflict of interest requirements. Don’t miss this timely session where you’ll learn more about the specific problems that arise from conflicts of interest such as how conflict of interest disclosure can smooth the formation of start-up companies and protect access to crucial research funds. Find out how you can best manage conflicts of interest in your university setting.

Learning Objectives

- Recognize the types of conflicts of interest that can arise as the result of university research efforts.
- Identify specific conflict of interest situations and how they have an impact on the activities of a technology transfer office.
- Understand the activities and concerns of Congress such as investigations into university research conflicts of interest and the possible results of these investigations.
- Understand how funding agencies are responding to concerns over conflicts of interest.
- Learn effective management techniques that universities and technology transfer offices can practice to manage conflicts.
- Recognize who the technology transfer office should be communicating with and when.

Scenario focus...questions welcome!
Key Stakeholders

• **Government** (federal, state, local)
• **Universities**
  - administration
  - faculty
  - staff
  - students
• **Private sector** (industry and investors)
• **Community** (…also known as “taxpayers”)

Preview

Perspectives

Scenarios

Lessons Learned

(…or “Learning!”)
Perspectives

“Keyhole Theory of Management”

Conceptual Overview

- **National** perspective (Susan)
- **Institutional** perspective (Dave)
- **TTO** perspective (Chris)
- *But, we should navigate all three!*
National Perspective

- **Dueling messages** of research partnerships/technology development and high intolerance for conflicts of interest
- **Congressional interest** in conflicts of interest, including institutional conflicts of interest
- NIH’s consideration of new federal regulations for investigator AND institutional conflicts of interest
- Proposed AAHRPP accreditation standards have amplified focus on addressing conflicts of interest
- Highly stressed university revenues and budgets

Institutional Perspective

- Though a small proportion of total research funding to universities, industry funding contributes to the **public good**.
- Industry funding can be an important component for **supporting students**
- Investigators and administrators must **remain transparent** in disclosing conflicts
- Most conflicts of interest **can be managed** rather than eliminated
- **Academic integrity is paramount** to any individual industry sponsored project
• TTOs tend to do things that **contribute to COI management needs.**

• **COI management involves important principles** of behavior that, while not new, haven’t received as much attention as they deserve.

• **What we are doing hasn’t changed** as much as the context has shifted.

• So, we need to be mindful that how we help the COI management process is an **evolving practice** (…and that’s not unusual in the TTO business!).

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**Action Themes**

“**Discovery through Disclosure**”

“**Mitigation through Management**”
Case Study No. 1

- A faculty member owns a small business which is the successful recipient of a SBIR award from NIH. The faculty member desires to subcontract a portion of the work back to himself via your institution.

- What is the conflict?

- How can it be managed?
Case Study No. 2

- A faculty member receives permission to take six months off to get his start up company off the ground. During this time it is discovered that the faculty member continues to work on-campus in his lab.

- What is the conflict?

- How can it be managed?

Case Study No. 3

- A department head calls you and states that there are people working in one of his faculty member’s labs that are not employees of the department.

- What is the conflict?

- How can it be managed?
Case Study No. 4

- A faculty member has an equity interest in a start up that is in your institution’s corporate park. The start up desires to hire graduate students to assist with IT support, data base management, and programming.

- What is the conflict?

- How can it be managed?

Case Study No. 5

- Your institution’s provost remains active in research and was recently informed that one of her discoveries shows the potential to revolutionize the treatment of leukemia. A major IP licensee desires to fund a large nationwide clinical trial.

- What is the conflict?

- How can it be managed?
Lessons Learned

Discussion and Q&A

Click the raise hand button or chat with us.

When called on, press * 7 on your telephone keypad to un-mute your phone.

When finished, press * 6 to mute your phone and click the lower hand button.
Takeaways – High Level

• Public spotlight never brighter on COI than today…get ready for heightened COI disclosure and management requirements.

• NIH likely to include COI more prominently in its regulatory strictures.

• Royalties are a big focus, especially if the resulting product/service is used at the royalty-earning university.

• Caution flags should go up anytime human subjects are involved.

• Spotlight, too, on Bayh-Dole under the lens of 2009, not 1980.

Key Action Steps At Home

• Communicate across the university (e.g., TTO and sponsored research office).

• Focus on ethics and integrity.

• Know that compromise is essential.

• Become members of your university COI committees.

• Working with public affairs shops is imperative.

• Institutional integrity preservation is key!
Concluding Points

• COI can easily arise from university research.
• COI is definitely of interest to TTOs.
• Congress is keenly interested in COI.
• Funding agencies are concerned about COI.
• Thus, COI is something universities need to address.
• And, prudent communication by TTOs is essential.

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Promoting the Role of the Technology Transfer Office Within Your University

Tuesday, September 22, 2009
12 p.m. – 1:30 p.m. Eastern

Featuring:
Chris D. McKinney, Vanderbilt University
Todd T. Sherer, Ph.D., Emory University

www.autm.net/OnlineLearning

Triage

Tuesday, September 29, 2009
12 p.m. – 1:30 p.m. Eastern

Featuring:
Joseph D. Fondacaro, Ph.D., Cincinnati Children's Research Foundation
R. Page Heller, The Texas A&M University System

www.autm.net/OnlineLearning
Managing Stakeholder Expectations
Tuesday, October 13, 2009
12 p.m. – 1:30 p.m. Eastern

Featuring:
David L. Gulley, Ph.D., University of Illinois at Chicago
Cameron McCoy, University of Oklahoma
Kristin Rencher, M.B.A., Oregon Health & Science University

Managing Priorities in Lean Academic Times
Wednesday, October 28, 2009
12 p.m. – 1:30 p.m. Eastern

Featuring:
Monya Dunlap, University of Florida
Patricia Weeks, Weeks Consulting LLC
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• Negotiations
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