



## Don't let your Conflict of Interest make you a Person of Interest: Perspectives from a University and Academic Medical Center

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## Agenda

### Setting the Stage

- History
- Our Challenge
- In the News (Headlines)

### Creating a Comprehensive COI Policy

- Our Definition – Conflict of Interest
- Components of a comprehensive COI policy
- Other policies considered

### COI Red Flags

- Outside Industry Agreements
- Vendors on Campus

### Healthcare Industry Sponsored Activities

- Educational Activities Funded by Health Care Industry Sources



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## Setting the Stage (History)

### Vanderbilt University & Vanderbilt University Medical Center

- Private Institutions
- University has 6,000 employees; Medical Center has 22,000+ employees
- Students not required to disclose
- VUMC physicians may have VU faculty appointments
- VU and VUMC Boards require 100% Compliance for all faculty and staff.

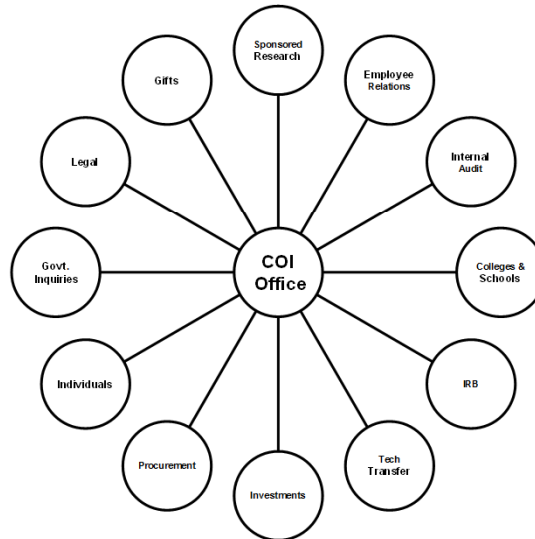
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## Setting the Stage – Our Challenge

- Vanderbilt's reputation. (Headlines)
- Built training into the questionnaire. Additional PHS training added when regulations updated 2012.
- 2016 VU and VUMC COI offices separated with shared systems.
- 2018 COI Systems Separated

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## Setting the Stage – Exchange of Information



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## In the News - Headlines

### THE TENNESSEAN

#### Vanderbilt discloses deals with old friends Entities had ties to trustees, officers at the university

5:13 AM, Jul 3, 2012 | 4 Comments

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Chancellor Nicholas S. Zeppos

Written by  
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The Tennessean

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Vanderbilt University did millions of dollars' worth of business with companies and other entities with ties to university trustees and officers, according to its most recent tax return, which covers the fiscal year ending June 30, 2011.

The transactions, the university's latest tax return shows, totaled about \$70 million, quadruple the \$17 million reported the year before. University officials released a copy of the return, known as a 990, last week. The listings include payments to and from Vanderbilt and entities linked to trustees and officers of the university.

Because it includes a hospital facility, Vanderbilt, under recent IRS rule changes, is required to file a more

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## In the News - Improvement



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## Creating a Comprehensive COI Policy

### Our Definitions:

A **Conflict of Interest** refers to a situation in which an individual's financial, professional, or other personal considerations may directly or indirectly affect, or have the appearance of affecting, an individual's professional judgment in exercising any VU/VUMC duty or responsibility, including the conduct or reporting of research. Typically, a Conflict of Interest may arise when an individual has the opportunity or appears to have the opportunity to influence VU/VUMC's business, administrative, academic, patient care, research, or other decisions in ways that could lead to financial, professional, or personal gain or advantage of any kind, whether or not the value is readily ascertainable.

A **Conflict of Commitment** refers to a situation where an individual engages in external activities, either paid or unpaid that interfere with his/her primary obligation and commitment to VU/VUMC.

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## Components of a Comprehensive COI Policy

- Administration Guidelines
- Business relationships
- Assets
- Research Activities
- Students
- Family Members
- Gifts and Contributions – Free lunch?
- Healthcare Sponsored Activities
- Educational activities funded by Healthcare Industry

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## Other policies considered when creating the comprehensive COI policy

- Vendors on Campus
- Vendor Solicitation Policy
- Pharmacy Policy Manual

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## COI Red Flags

- Seeing extravagant gifts received from vendors
- Employees with same last names working together
- Using the institution's name or logo on the employee's business website
- Soliciting to co-workers by leaving business cards and marketing brochures around

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## COI Red Flags – Outside Industry Agreements

- Use of Vanderbilt-owned equipment
- Use of Vanderbilt-owned space
- Staff involvement – (i.e., staff performing work for outside company)
- Vendors coming on-site
- Presentations being made on behalf of a company
- Marketing

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## COI Management Plan

Questions to consider:

- Is it a Conflict of Interest?
- Is it a Conflict of Commitment?
- Is it manageable?

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## Vendors on Campus

- All vendors must be registered with the Vendor Liaison Office (VLO) (for medical and surgical vendors) or the Pharmacy (for pharmaceutical vendors)
- Must schedule an appointment
- Must check in with the VLO or the Pharmacy for the day of the appointment
- Must obtain and wear an official ID badge or a guest pass issued by the VLO or the pharmacy

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## Healthcare Industry-Sponsored Activities

The Health Care Industry is considered as suppliers of pharmaceuticals, medical equipment and devices, or medical service vendors or their agents.

VUMC personnel may not participate in or receive compensation or consulting pay of any amount:

1. For listening to sales talks or simply attending a continuing medical education (CME) or other activity where the vendor is paying participants to attend the event.
2. For prescribing medications or changing a patient's prescription.

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## Educational Activities Funded by Healthcare Industry Sources

Provision of funds from Healthcare Industry sources to support activities by VUMC personnel (i.e., scholarships, reimbursement of travel expenses, or other non-research funding in support of scholarship or training) must be free of any actual or perceived Conflict of Interest, whether the funds are provided directly to VUMC or indirectly through industry grants to professional organizations.

- Industry may not earmark contributions to fund specific recipients or to support specific expenses.
- Funds must be provided to the VUMC department or the sponsoring professional organization rather than directly to the trainee.
- The VUMC personnel must be selected according to clear criteria.
- The VUMC department must determine that the conference or training has educational merit.
- The recipient of the funds must not be subject to any implicit or explicit quid pro quo.

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## COI Review Committees

VU – University Conflicts Committee (UCC)

VUMC – Medical Center Conflict of Interest Committee (for VUMC employed Faculty)

VUMC – Staff COI Committee (for all others)

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## Case Scenario

Members of the IT team have been invited to have lunch with representatives from Barney's Rapid Recovery Company, a Disaster Recovery Planning tool vendor, at an upcoming conference, that will be attended by current and prospective Barney's customers. Earlier this year an RFP for a disaster recovery tool was conducted and Barney's ended up as the tool of choice, to the point where we were days away from signing a contract only to have the Executives have a change of mind and place the initiative on indefinite hold. We have an established relationship with this vendor and hope we'll be able to procure their tool sometime in the future.

Can the team attend this lunch? Is this a COI?

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## Case Scenarios

- One of my faculty members is a paid consultant for two device companies. Each company would also like her to test these devices in a clinical trial. Is this a conflict of interest?
- One of my PIs just received a large NIH grant. He would like to do a subcontract with a nearby institution. When I asked, he told me the subcontract PI is his wife. This doesn't feel right, is it okay?

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## Questions



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