

# Financial Conflict of Interest Training

This module is required for all Vanderbilt Faculty and Staff who receive support through the Public Health Service (PHS).

*Training provided by:*

VU Office of Conflict of Interest and Commitment Management

# Upon completion of this training module, you will be able to:

- Identify key changes to the Federal regulations involving the reporting of Financial Conflicts of Interest related to:
  - Definitions
  - PHS Investigator Disclosure Responsibilities (e.g., what must be disclosed)
  - Institutional Role for Review and Reporting
- Understand the process by which your financial relationships must be disclosed and reviewed prior to expenditure of federal funds.

# Outline

- Historical reference
- Purpose of the regulations
- Key changes
- Definitions
- Requirements for disclosure
- Requirements for review
- Responsibilities – Investigator
- Responsibilities – Institution
- Examples
- Reference and Contact Information

# Historical Reference

- Vanderbilt University has had a ***Conflict of Interest*** disclosure and review process for many years, meeting compliance with the initial federal regulations issued in 1995.
- In August 2011, the Department of Health and Human Services, acting through the Public Health Service (PHS), issued its final rule amending the regulations on *Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought* (42 CFR 50, Subpart F) and *Responsible Prospective Contractors* (45 CFR 94).
- All changes were implemented before the **August 24, 2012** deadline and applied to **all** *Notice of Grant Awards* issued after this date.

# Purpose of the PHS Regulation

The purpose of the regulation is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research will be free from bias resulting from Investigator financial conflicts of interest.

# Key Changes to the PHS Regulation

- The **Significant Financial Interest (SFI)** threshold was reduced from \$10,000 to \$5,000 annually and/or **any** equity holding in a non-publically traded company.
- *All reimbursed or sponsored **travel** related to institutional responsibilities\** must be disclosed to Vanderbilt regardless of the amount.
- All federally funded investigators and key study personnel must complete training initially upon submission of a grant application, and every four years following. **This module** meets the requirement for your initial and renewal training.

*\*See definitions on [slides 9-12](#)*

# Key Changes to the PHS Regulation

Vanderbilt is required to complete a **scientific review** for any award in which an investigator has an SFI. The scientific review will determine whether any such SFI constitutes a Financial Conflict of Interest (FCOI), and if so, how this will be managed or eliminated.

When it is determined that an FCOI exists, management plans must be reported back to the awarding agency before grant funds are spent, and updated at least annually.

# Key Changes to the PHS Regulation

Vanderbilt is required to respond to requests for information from the public to include:

- The conflicted investigator/key study personnel's name
- Title
- Entity in which there is an SFI
- Nature of the financial interest (e.g., consulting, board service)
- Value of the interest



# PHS Definitions

- **Investigator** – the Project Director (PD) or Principal Investigator (PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research, including sponsored research or proposed sponsored research.
- **Senior/Key Personnel** – any Member of the University Community named as the Principal Investigator, project director, or otherwise identified as senior/key personnel by the University in a grant application, progress report, or any other report submitted to the PHS by the University.
- **Institutional Responsibilities** – a Member of the University Community's activities and duties on behalf of the University or which fall within the scope of employment by the University (e.g., such as research, consultation, teaching, professional practice, institutional committee memberships, and service on panels such as the Vanderbilt University IRB or the IACUC).

# PHS Definition: **SFI**

**Significant Financial Interest (SFI)** – A financial interest consisting of one or more of the following (also included is the financial interest of your spouse or dependent children):

- The value of any remuneration and/or equity interest exceeds \$5,000 [when received in the twelve months preceding, and in aggregate].
- Any equity interests in a non-publically traded company.
- Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- Any reimbursed or sponsored travel related to activities deemed to be part of your institutional responsibilities.

# Exclusions from the SFI Definition:

- Salary, royalties or other remuneration paid by Vanderbilt.
- IP income paid through Vanderbilt's Center for Technology Transfer & Commercialization.
- Income from mutual funds and/or retirement accounts so long as you do not have direct control over investment decisions.
- Income from seminars, lectures, teaching, service on advisory committees or review panels, for a federal, state or local governmental agency, an institution of higher education (as defined by 20 USC 1001(a)), an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education.

# PHS Definition: **Financial Conflict of Interest (FCOI)**

A **Financial Conflict of Interest (FCOI)** is significant financial interest (see definition on previous slide) that could directly and significantly affect the design, conduct, or reporting of research.

# Responsibilities – PHS Investigator

- Faculty & Staff must disclose all outside business and other relationships to Vanderbilt at least annually.
- Disclosures must be updated within 30 days of the acquisition of a new financial interest.
- Investigators must verify the completeness of their disclosure upon submission of a new federally funded grant or contract.
- Investigators must affirm at least annually and upon each submission of a federal grant, their understanding of and agreement to follow Vanderbilt's Conflict of Interest and Commitment policy.
- Investigators must complete training on the topic of Conflicts of Interest, initially upon submission of a federal grant, when indicated for re-training (e.g., change in Vanderbilt COI policy or Investigator non-compliance with management plan), and every four years.

# Responsibilities – PHS Investigator

- Please note that all faculty and staff (and family members) must disclose Board memberships, which may include being an officer or director of a business, whether or not the position is compensated, as part of the requirements for disclosure under the Vanderbilt Conflict of Interest and Commitment Policy.
- Disclosure is also required if the individual or family member is an employee, consultant, faculty member, or advisor for the business.

# Responsibilities – Vanderbilt

- Maintain a Conflict of Interest Policy that is in compliance with the federal regulations and publically available for review via the VU and VUMC Compliance Office websites.
- Maintain records of all COI documentation of review and actions related to conflicts of interest for at least three years from the date of submission of the final expenditures report.

# Responsibilities – Vanderbilt

Review all disclosures and determine whether relationships reaching the level of a significant financial interest constitute a Financial Conflict of Interest (FCOI), and if so:

- Develop a management plan.
- Provide management plans to the PHS awarding agent prior to the expenditure of funds, within 60 days of identifying a new FCOI, and annually.
- Make available at the public's request the following:
  - Investigator's name and title
  - Role within the funded project(s) (e.g., PI)
  - Name of entity in which there is an SFI
  - Nature of SFI (e.g., payments for consulting)
  - Approximate dollar value of the SFI in ranges (e.g., \$0-\$4,999), or a statement that the value cannot be readily determined.



# Example

- Dr. Smith has a consulting relationship with Company Alpha in which he is paid as a consultant. As part of this agreement, he was paid for his services, \$12,000 in the 12 months prior, and was reimbursed travel expenses on three trips with a value of \$3,000 per trip.
- Dr. Smith is the PI on a study being submitted to the NIH for funding. The AIMS of this study overlap with the consulting work he is doing with Company Alpha.

*Under Vanderbilt's Conflict of Interest and Commitment Policy, what must Dr. Smith do?*

# Answer

- Dr. Smith must disclose this business on his annual Conflict of Interest Disclosure Form, *including travel reimbursements*.
- When submitting the grant to the NIH, Dr. Smith must verify that he disclosed this relationship in his annual form and make any additional disclosures in an updated disclosure, as needed.
- Upon receipt of the Just-in-Time (JIT) Notice or Notice of Grant Award (NOGA), Dr. Smith must verify that the COI review has been completed and a management plan established PRIOR to expending funds from the grant.
- It will be Dr. Smith's responsibility to follow all safeguards that are included in the management plan.
- Penalties for deliberate violations of this policy will be adjudicated in accordance with applicable disciplinary policies and procedures of the Human Resources Staff Guidelines or the Faculty Manual, as applicable.

# Example Timeline (disclosure to reporting)

\*All relationships must be in compliance with the University and VUMC COI Policies.

\*\*Other processes, such as required IRB approval for human subjects research, are not included on this timeline, but may be required for final approval.

## Investigator Action

Consulting contract signed by faculty or staff \*

Annual Disclosure Process Faculty discloses consulting agreement

Submit Grant Application & Complete PEER COI Disclosure

JIT Notice or NOGA Received

Grant funds may be dispersed

COI Eliminated or Managed\*\*

Review Process - Departments

Review Process - COI Office

Review Process - Scientific Review

Review Process - COI Office and/or UCC (If required)

Management Plan reported to NIH

Annual report to NIH (Submitted with Progress Report)

## Institutional Response

# Example Timeline (disclosure to reporting)

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## Investigator Action

Annual Disclosure Process  
Faculty discloses consulting agreement

Submit Grant Application & Complete PEER COI Disclosure

JIT Notice or NOGA Received

Grant funds may be dispersed

Consulting contract signed by faculty/staff \*

**COI Eliminated or Managed\*\***

Review Process -  
Departments

Review Process -  
COI Office

Review Process -  
Scientific Review

Review Process -  
COI Office and/or UCC (If required)

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Annual report to NIH (Submitted with Progress Report)

## Institutional Response

# Key Take-Away Points!

- The threshold for SFI is now \$5,000 and includes **any** interest in a non-publically traded company.
- Investigators must **disclose** relationships to Vanderbilt. Vanderbilt must determine whether the SFI is a Financial Conflict of Interest (FCOI) and if so, take steps to eliminate or manage the FCOI.
- Management plans must be **reported** to NIH upon initial NOGA, before expenditure of funds. Updates will be required annually to the NIH.
- If you have a **new** potential COI develop, you must disclose this to Vanderbilt within **30 days**.
- All FCOIs may be made public through an online inquiry system.

# Online Resources at Vanderbilt

## **COI Disclosure Systems:**

COI Disclosure System for University Faculty and All Staff

<https://webapp.mis.vanderbilt.edu/coi/>

COI Disclosure System for VUMC Faculty

<https://medapps.mc.vanderbilt.edu/coi>

## **COI Policy:**

Vanderbilt University COI Policy

<http://www.vanderbilt.edu/compliance/includes/CurrentCOIPolicy.pdf>

# Online Resources from PHS & NIH

## NIH Grants Policy

<http://grants.nih.gov/grants/policy/coi/>

## COI Final Rule issued August 25, 2011

[http://grants.nih.gov/grants/policy/coi/fcoi\\_final\\_rule.pdf](http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf)

## Summary of Major Changes to COI Policy

[http://grants.nih.gov/grants/policy/coi/summary\\_of\\_major\\_changes.doc](http://grants.nih.gov/grants/policy/coi/summary_of_major_changes.doc)

## PHS Tutorial

<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>

# Contact Information

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# The End

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