



VANDERBILT UNIVERSITY
Office *of* the General Counsel

Financial Conflict of Interest Training for Investigators

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

Understand 2022 updates to Vanderbilt's COI policy.

Understand 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

- **Purpose of the regulations**
- **2022 changes to Vanderbilt COI Policy**
- **Definitions**
- **Requirements for disclosure**
- **Requirements for review**
- **Responsibilities – Investigator**
- **Responsibilities – Institution**
- **Examples**
- **Reference and Contact Information**

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 Elements of the PHS Regulation

The **Significant Financial Interest (SFI)** threshold (at which an investigator must disclose interests) is \$5,000 annually and/or **any** equity holding in a non-publicly 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 this training obligation.

*See definitions on slide 10

2022 Changes to Vanderbilt COI Policy

FOREIGN SUPPORT DISCLOSURE

Updated policy provides guidance to researchers related to foreign support

SIGNIFICANT FINANCIAL INTEREST DISCLOSURES

Updated policy limits the significant financial interest disclosures required

Foreign Support Guidance

Examples of foreign support that **must be disclosed** by all Investigators on federal grants (and that may need to be disclosed to other sponsors), include:

(a) all **positions and affiliations**, including volunteer positions, relevant to an individual's research endeavors

(b) relevant **appointments at foreign Institutions** – even if labeled as “guest,” “adjunct,” “honorary,” with or without salary support

(c) **income, salary, consulting fees, and honoraria** in support of an individual's Research endeavors

(d) participation in a **foreign talent** or similar-type programs

(e) all **resources and other support**, both domestic and foreign, for ongoing Research projects, including those conducted at a different Institution

(f) **in-kind contributions** from domestic and foreign Institutions or governments that support Research activities

(g) **travel** paid by a foreign Institution or government

(h) **Financial Interests** received from a foreign Institution of higher education or a foreign government

To review the source of this guidance from PHS, see the following link:
<https://grants.nih.gov/policy/protecting-innovation.htm>.

Significant Financial Interests

In addition to their own interests, investigators must disclose the significant financial interests of their spouse and dependent children.

Investigators are no longer required to disclose financial interests of *all family members*

This change was made to align the Vanderbilt policy with PHS policy.

Key Requirements of the PHS Regulation

Vanderbilt is required to complete a **scientific review** for any award when 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 the FCOI 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. This report must be updated at least annually.

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 Covered Individual 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 Covered Individual's activities and duties on behalf of the University or which fall within the scope of employment by the University (e.g. research, consulting, teaching, professional practice, institutional committee memberships, and service on panels).

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 interest in a non-publicly 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 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.

Note: Vanderbilt may require disclosure of activities on this exclusion list for purposes other than PHS compliance. Please carefully read and accurately answer all disclosure questions

PHS Definitions: FCOI

Financial Conflict of Interest (FCOI)

A significant financial interest that could directly and significantly affect the design, conduct, or reporting of research.

Responsibilities: PHS Investigator

- Investigators must disclose all required relationships to Vanderbilt at least annually.
- Disclosures must be updated within 30 days of the acquisition of a new significant 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: Vanderbilt

Maintain a Conflict of Interest Policy that is in compliance with the federal regulations and publicly available for review via the Vanderbilt Office of Conflict of Interest and Commitment Management website.

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.

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 thereafter.
- 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.

Other Funding Sources

Many funding sources follow PHS regulations related to conflicts of interest.

[This link on the COI website](#) provides a list of funding sources that follow PHS regulations.

Example Situation

Question:

Professor A has a consulting relationship with Company B in which he is paid as a consultant.

He is paid \$12,000 in the 12 months prior and was reimbursed travel expenses on three trips with a value of \$300 per trip.

Professor A 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 B.

Under Vanderbilt's COI Policy and procedures, what must Professor A do?

Answer:

- Professor A must disclose his consulting relationship on his annual Conflict of Interest Disclosure Form, including travel reimbursements.
- When submitting the grant to the NIH, Professor A must verify that he disclosed this relationship in his annual form and update his disclosure if new consulting relationships arise.
- It will be Professor A's responsibility to follow all provisions of his 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.

Key Takeaways!

The **threshold for SFI** is \$5,000 and includes **any** interest in a non-publicly traded company.

Investigators must **disclose their 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 PHS/NIH, before expenditure of funds. Updates will be required annually to the NIH.

If you have a newly developing potential COI, you must **disclose this to Vanderbilt within 30 days**.

All **FCOIs may be made public** (upon request) through an online inquiry system.

Vanderbilt Online Resources



[Conflict Disclosure System](#)



[COI Office Website](#)



[Conflict of Interest Policy](#)

PHS & NIH Online Resources

[NIH Grants Policy](#)

[COI Final Rule issued August 25, 2011](#)

[Summary of Major Changes to COI Policy](#)

[PHS Tutorial](#)

Office of Conflicts of Interest and Commitment Management

The **Office of Conflicts of Interest and Commitment Management** strives to provide excellent services to our customers, and our website includes many conflict of interest resources.

Please feel free to contact us if you have any questions or would like our office to provide conflict of interest training to your University department.

CONTACT US

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Visit our website for additional resources:

www.vanderbilt.edu/generalcounsel/coi