

Welcome to Thomas Jefferson University's Financial Conflicts of Interest Tutorial



NOTICE

According to Thomas Jefferson University's Conflicts of Interest Policy for Employees, all covered persons responsible for the design, conduct, or reporting of PHS-sponsored research must complete Financial Conflicts of Interest training prior to engaging in research related to any PHS-funded grant or contract and at least every four years.

Immediate training is required under the following circumstances:

- *When the University's COI policies change in a manner that affects Investigator requirements;*
- *When an Investigator is new to the University; and*
- *If the University finds an Investigator noncompliant with the University's COI policy or management plan.*

This tutorial is designed to satisfy the training requirements outlined in TJU Policy No. 107.03.

LEARNING OBJECTIVES

- To provide an overview of federal regulations governing financial conflicts of interest.
- To outline and explain Thomas Jefferson University's Conflicts of Interest Policy requirements.
- To provide guidance regarding disclosure of financial interests and outline procedural processes related to identification, review, and management of financial conflicts of interest.

Federal Regulations Governing Objectivity in Research

- The Code of Federal Regulations promotes objectivity in research by establishing standards to ensure that the design, conduct, and reporting of research funded under federal grants, cooperative agreements, or will not be biased by a conflicting financial interest of an investigator.
- **View the 2011 Public Health Service (PHS) Regulations:** Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought at ([42 C.F.R. Part 50, Subpart F](#)) and policies governing Responsible Prospective Contractors at ([45 C.F.R. Part 94](#)).

Fundamental Requirements of the Public Health Service Regulations

- These regulations apply to each Institution that applies for or receives PHS research funding by means of a grant or cooperative agreement and to each Investigator seeking to participate in such research. *SBIR Program Phase I applications are exempt from these requirements.*
- Under the regulations, Institutions seeking NIH support for research must establish:
 - a written policy and process to identify and manage COI
 - an institutional COI officer
 - an institutional COI committee
 - a COI disclosure and review process allied with the submission, review, and approval processes for research grants and IRB protocols

Thomas Jefferson University's Policies Designed to Address and Manage Conflicts of Interest

The following University policies relate to conflicts of interest, and interface with the Conflicts of Interest for Employees Policy:

Policy Number	Title
107.17	CONFLICT OF INTEREST POLICY: DISTRIBUTION TO NEW EMPLOYEES
107.03	CONFLICTS OF INTEREST POLICY FOR EMPLOYEES
102.13	CONFLICTS OF INTEREST POLICY FOR THE BOARD OF TRUSTEES
102.15	PATENT POLICY
102.37	POLICY ON EQUITY ACCEPTANCE, HANDLING & OF TECHNOLOGY LICENSING ARRANGEMENTS
102.42	INSTITUTIONAL CONFLICT OF INTEREST POLICY
107.25	INDUSTRY RELATIONSHIPS POLICY

TJU Conflicts of Interest Policy for Employees

- TJU maintains a Conflict of Interest Policy for Employees (Policy Number 107.3), which satisfies regulatory requirements ([42 C.F.R. Part 50, Subpart F](#)) and [45 C.F.R. Part 94](#)) and safeguards the integrity of academic medicine and biomedical research.
- Policy Number 107.03 is available at <http://www.jefferson.edu/counsel/coi.html>
- The Policy consists of six parts:
 - Policy
 - Attachment 1: Statement of Principles (PDF)
 - Attachment 2: Operating Definitions (PDF)
 - Attachment 3: Disclosure of Significant Financial Interests & Activities (PDF)
 - Attachment 4: Statement for Non TJU/Non TJUH Employees Conducting Research
 - Attachment 5: Public Disclosure Form

WHO IS COVERED UNDER THE UNIVERSITY'S COI POLICY

- **Covered individuals** are faculty (full-time, part-time, or non-salaried), key personnel, or administrators who are investigators; have a management position or above; whose job responsibilities affect purchasing, operating and/or financial decisions of the University or Jefferson University Physicians; and/or who have a significant responsibility with respect to sponsored or non-sponsored research projects.
- **Covered individuals** also include faculty, key personnel, or administrators who, under the aegis of the University or pursuant to the review and approval of the University's IRBs, conduct research.
- **Family members** of a covered individual include his/her spouse, dependent children, and all other persons living in the same household.
- **Volunteer faculty**: Individuals holding volunteer faculty appointments are not required to complete COI certifications unless they are involved in research administered through TJU's ORA and/or IRB.

The University's Policy Operates to Identify Potential Conflicts of Interest

- The Policy contains a disclosure mechanism whereby covered individuals regularly review and disclose to the University their financial interests that appear to bear relationship to their institutional responsibilities.
- Covered individuals must submit a COI Disclosure at the time of hiring or appointment and thereafter on an annual basis.
- Covered individuals must update their COI Disclosure statement upon receipt of notice of a change in financial status.
- Disclosure of financial interests is required upon filing of an ePTF, application for IRB approval, notice of invention, and upon request of the Conflicts of Interest Officer and/or the Standing Committee on Conflicts of Interest.

Continuing Obligation to Disclose



If at any time between disclosure processes, an individual becomes aware of a change in his/her financial circumstances that would appear to be reasonably related to their institutional responsibilities or a new relationship with an entity arises, the situation must be disclosed at the earliest possible time.

Covered persons must disclose financial interests.

Financial Interest Defined:

Any interest that will, may, or is intended to lead to a profit or an increase in the income or net worth of an Employee, Investigator, Dependent, or other covered persons under the COI policy.

Some examples of financial interests include:

- Payments of any kind (e.g., salary, consulting fees, honoraria, gifts, dividends, distributions, rent, paid authorship, etc.),
- Equity Interests, an increase in the value of real estate or Equity Interests, or Intellectual Property Rights

EVALUATION OF DISCLOSED INTERESTS



IDENTIFYING A SIGNIFICANT FINANCIAL INTEREST

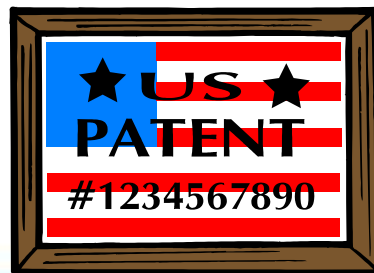
A financial interest held by an Investigator and/or an Investigator's covered family member that reasonably appears to be related to the Investigator's Institutional Responsibilities.



The \$5,000.00 disclosure threshold does not automatically determine whether a significant financial interest exists.

What are Considered Significant Financial Interests (SFIs)?

- Consulting fees, honoraria, or gifts \geq \$5,000
- Equity interests or options \geq \$5,000 ownership in a publicly traded company
- Equity interests of any amount in a non-publicly traded company
- Any Intellectual Property Rights, regardless of value, upon receipt of income related to such rights and interests.
- **(PHS sponsored projects only):** certain reimbursed or sponsored travel related to Institutional responsibilities. This disclosure requirement does not apply to travel that is reimbursed or sponsored by federal, state or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center or a research institute that is affiliated with an institution of higher education.



What are not Significant Financial Interests?

- Intellectual Property Rights assigned to the University and agreements to share in royalties related to such rights;
- Salary, royalties, or other remuneration paid by the Institution to a currently employed Investigator;
- Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
- Income from seminars, lectures, or teaching engagements sponsored by a federal, state or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education;
- Income from service on advisory committees or review panels for a federal, state or local government agency, Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

IDENTIFYING A FINANCIAL CONFLICT OF INTEREST

A Financial conflict of interest (FCOI) is a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research.

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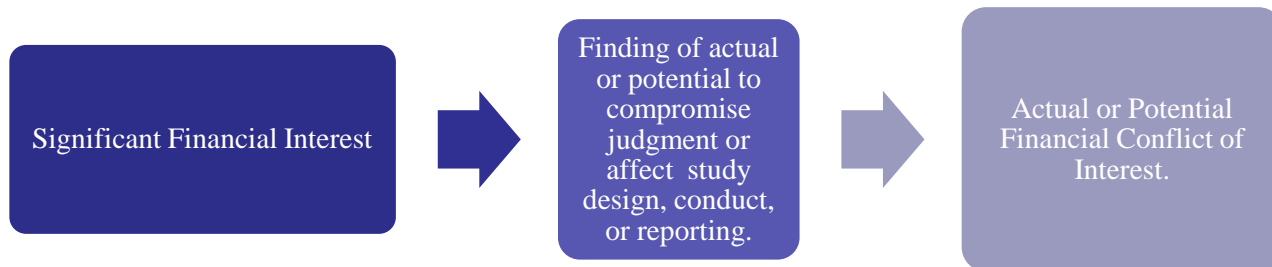
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Finding Financial Conflicts of Interest

The COI Committee will evaluate whether the covered person's significant financial interest compromises, or could appear to compromise, his or her professional judgment regarding the design, conduct or reporting of research or if the significant financial interest could directly and significantly affect the design, conduct or reporting of research.



TJU COI Policy Operates Under the “Rebuttable Presumptive Prohibition” Concept for Individuals with Financial Conflicts of Interest

- To assure that all potentially problematic circumstances are reviewed, the COIC Committee presumes that a person with a financial conflict of interest may not conduct the research in question or engage in the activity in question.
- This presumptive prohibition is rebuttable to the COIC Committee by demonstration of compelling circumstances and proposal of a management plan.
- Review and acceptance by the Committee of a rebuttal, with the imposition of a management plan in lieu of elimination of the financial conflict of interest, is subject to further review and approval by the President.

What are Potentially Compelling Circumstances?

- Facts that the COIC Committee considers to determine whether the individual should be permitted to engage in the conduct in question, include:
 - the nature and magnitude of the financial interest
 - the degree to which the interest is related to the activity
 - whether the individual is uniquely qualified to conduct the activity
 - the extent to which the activity is amenable to effective oversight and management
- For research, circumstances include the nature of the science, the degree of risk to any human subjects, and whether the research could not be conducted as safely or effectively without the interested individual.
- For research involving human subjects, the bar is very high.

Mechanisms to Eliminate, Reduce or Manage Financial Conflicts of Interest

Three possible ways to resolve a finding of a Financial Conflict of Interest: (1) reduce or eliminate SFI; (2) cease to engage in conflicting activity; or (3) propose an acceptable management plan. Plan elements may include some or all of the following:

- Public disclosure
- Disclosure to research subjects
- Monitoring of the research activity
- Modification of the research plan
- Disqualification from part or all of the research activity
- Escrowing or divestiture of financial interest
- Severance of relationships



Summary of COIC Committee Procedures

- Upon disclosing a financial interest, covered persons may receive correspondence from the COI Committee, seeking more information, identifying a potential COI, or identifying an actual COI requiring reduction, elimination, or management.
- Covered persons must respond in a timely manner to the COI Committee's correspondence.
- The COI Committee reviews all proposed FCOI management plans. If approved, the COI Committee transmits the proposed plan to the University President for approval.
- Covered Persons receive written notification of proposed management plan decisions.
- Research that is conducted under provisions of a conflict management plan will receive ongoing monitoring until the research project is completed.

POLICY PROVISIONS SPECIFIC TO PHS-SPONSORED RESEARCH

PUBLIC DISCLOSURE

- Upon receipt of a written request, the University will make available to the public information for senior and key personnel engaged on a PHS-sponsored project, regarding financial conflicts of interest related to active PHS-sponsored research. This information will include the investigator's name, title and role on the project; the name of the entity in which the financial interest is held; and the nature and approximate value (if it can be determined) of the financial interest.

(See the Public Disclosure Request Form at Attachment 5 to Policy No. 107.03).

REIMBURSED TRAVEL

- Investigators conducting PHS-sponsored research must disclose the occurrence of any reimbursed travel or sponsored travel related to University responsibilities over the previous twelve-month period no later than at the time of application for PHS-funded research.
- Employees are NOT required to disclose travel that is reimbursed or sponsored by a federal, state, or local government agency, a University of higher education as defined at 20 U.S.C. § 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an University of higher education.
- Each University Department is responsible for obtaining travel-related information from employees and transmitting to the Conflicts of Interest Committee any travel-related abnormalities or concerns.

ADDITIONAL RESOURCES

- 2011 Public Health Service (PHS) Regulations: Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought ([42 C.F.R. Part 50, Subpart F](#))
- Responsible Prospective Contractors ([45 C.F.R. Part 94](#))
- *Direct inquiries regarding the Financial Conflicts of Interest to the Office of University Counsel (215) 955 – 8585.*

This

Certificate of Completion

certificate is awarded to

in recognition of successfully completing

**THOMAS JEFFERSON UNIVERSITY'S
FINANCIAL CONFLICTS OF INTEREST TRAINING MODULE**

on

_____, 201____

Sonya Fair Lawrence

Sonya Fair Lawrence, J.D., B.S.N.
Conflicts of Interest Officer