



# Conflict of Interest: Policies Governing Outside Relationships and Mitigating Conflicts

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# Definitions

## Conflict of Interest

An outside relationship that conflicts with an individual's primary interests that may result in inappropriate influence, or the perception of such influence over the activities of the individual.

## Conflict of Commitment

An outside relationship that creates a risk of undermining an individual's primary interest.



# Disclosure Process

## Annual Disclosures

- Completed in the spring
- Zero-dollar reporting threshold
- Any changes to outside activities need to be disclosed within 30 days throughout the year

## Research Related Disclosures

- Each grant submission to any Public Health Service (PHS) agency for all Key Personnel
- Each IRB Protocol submission for Principal Investigators



# Scenarios: Individual COIs Involving Industry Collaboration

1

Individual has a relationship with a company and would like to participate in clinical research on that company's technology

2

Individual has a relationship with a company that wishes to sponsor research in the individual's laboratory

3

Holding an Executive or Board of Director role in a company

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# Mitigating COIs

## Clinical Research Rule:

- It is presumed that an individual that participates in clinical research may not have a financial interest exceeding the *de minimis* thresholds in a business whose technology is being investigated.

## De minimis thresholds

- Receive \$25,000 or less/year in aggregate in compensation from the business in the form of income (i.e., consulting fee)
- Hold \$50,000 or less in equity in the business if it's publicly traded
- **Any equity** in a private company is subject to this rule

**Petition Process** One may present a management plan, requesting the COI Committee grant an exception to the rule



# Mitigating COIs (cont.)

## Research Support Rule

- It is presumed that an individual who has an equity financial interest above the *de minimis* threshold in a business may not receive sponsored research support from that business.

## Executive Position Rule

- Full-time individuals may not hold an executive position in a for-profit business.
- Part-time individuals may hold approved executive positions but may not participate in the clinical research on the business's technology nor receive sponsored research support from the business.

## External Activity Rule

- Individuals who serve in a fiduciary role to a for-profit business may not participate in clinical research on the business's technology nor receive sponsored research support from the business.



# Public Health Service Agencies



## Investigator Disclosure Requirements

1. Prior to research;
2. Annually; and
3. Any time there is a change (within 30 days)

## COI Analysis Overview

- Institution responsible for determining:
  - Is there a Significant Financial Interest (SFI)?
  - Is the SFI related to the PHS funded research?
  - Could the financial interest be affected by the research?
  - Is there a Financial Conflict of Interest (FCOI) that needs to be managed?

**Significant Financial Interest (SFI):**

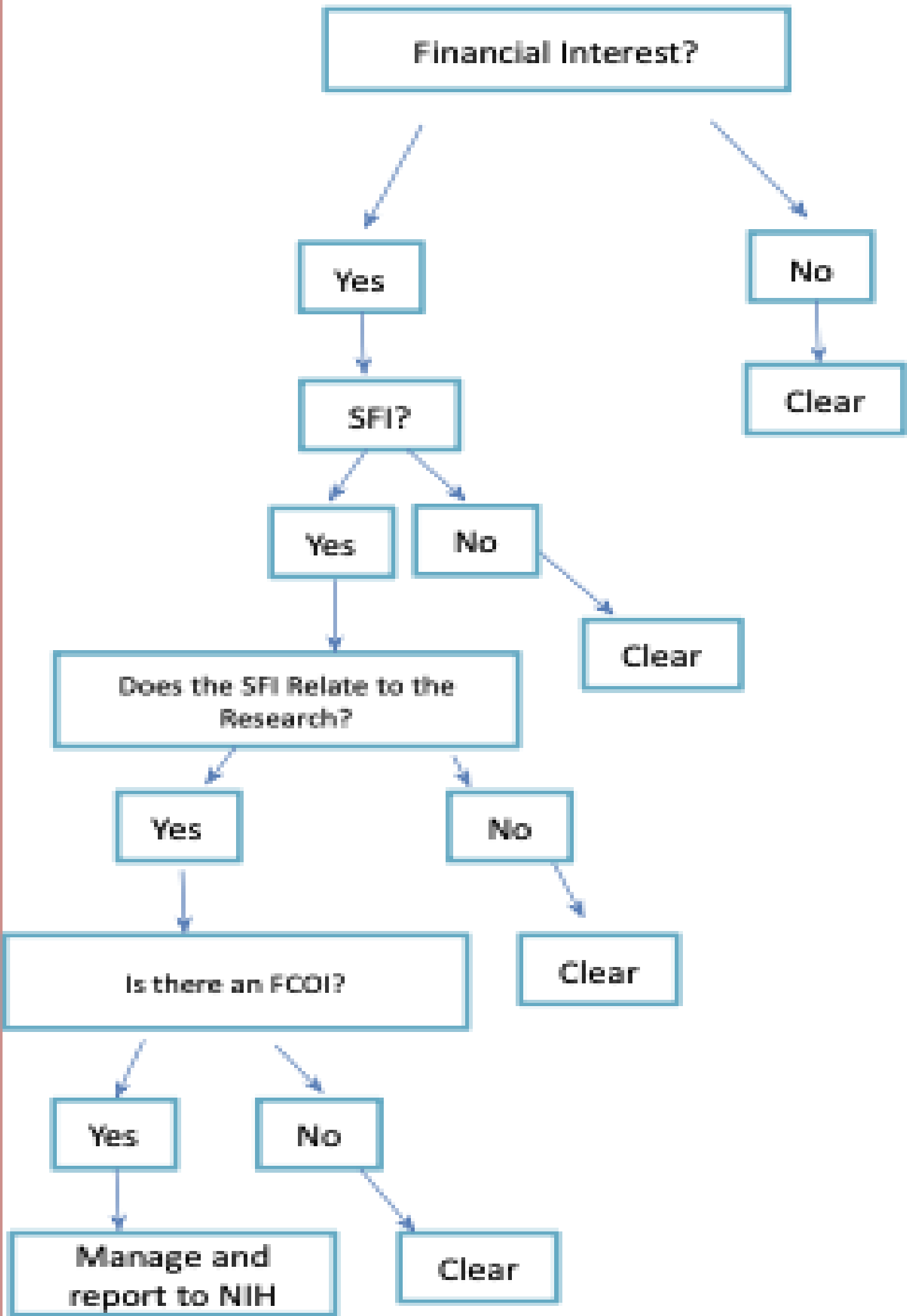
If the Investigator, spouse, dependent children receive \$5,000/year or above from an entity, hold \$5,000 or above in equity in a public company or any amount of equity in a private company.

**Does the SFI Relate to the Research?**

The SFI relates to the research if the SFI could be affected by the federally funded research or if the SFI is in an entity whose financial interest could be affected by the research.

**Is there a Financial Conflict of Interest (FCOI)?**

An FCOI exists if the SFI could directly and significantly affect the design conduct or reporting of PHS funded research.





# Common Outside Activities



## Speaking Engagements

- Generally permitted; recommend having a contract
- No Speaker's Bureaus:
  - Individual must retain intellectual independence over the content of any educational material they present



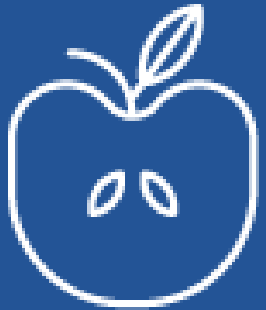
## Personal Consulting Agreements

- Establish process for Legal and Compliance review
- Incorporation of an institutional consulting rider



# Rules for Gifts and Meals

Individuals are prohibited from soliciting or accepting personal gifts and meals (whether paid directly on their behalf or reimbursed) from a pharmaceutical, medical device, biotechnology, or supply company.



## Meal Rule Exceptions

- Contractually Required Meetings Exception
- Education Exception
- Research Collaboration/ Funding Request Exception



## Gift Rule Exception

- Gifts from a company to an individual having a monetary value of less than \$100 in the aggregate in any one calendar year are permissible; and
- Gifts need to serve a care or educational purpose



# Open Payments

## Physician Payment Sunshine Act (2013)

- Requires disclosure of payments by pharmaceutical and medical device companies via a publicly searchable website
- Examples of reportable payments include:
  - Consulting payments
  - Honoraria, food, and beverage costs
  - Travel and lodging

**Please Note:** Even if the company is not technically paying you, but rather is transferring something of value (i.e., if the company covers your expenses), such payments need to be reported



# Institutional COIs



## Senior Leadership

- Heightened responsibility to identify and manage COIs
- Roles in institutional spin off companies
- Investing in institutional spin off companies



## Institutional Ownership in a Company

- Institution holds equity in a company
- Conducting research at an institution that holds equity in the company
- Institution using a company's product that it holds equity in



# Management of COIs



## Management Committee

- Draft and present COI management plans
- Provide compelling justifications for exemptions
- COI management plan outlines well-defined safeguards and restrictions



## Auditing & Monitoring Plans

- Establish periodic check-ins
- Identify material changes in COIs (i.e., role, financial position, company changes, etc.)
- Present plans to Committee for reapproval



# Defining a Conflict

## Conflict of Interest (COI)

A situation in which a Covered Individual (or a member of their family), has a financial or non-financial interest that may compromise, or provide the incentive to compromise, the Covered Individual's behavior in the conduct of their activities, their decisions, or their influence over their associates.

## Conflict of Commitment (COC)

A situation where a Covered Individual's commitment to Outside Professional Activities adversely affects their capacity to meet their professional responsibilities.



# Disclosure of Outside Activities & Interests

## Disclosures required per policy:

- Ownership interests in interested organizations\*
- Ownership interests in non-interested organizations\*
- Official positions in interested & non-interested organizations
- Consulting engagements
- Remuneration from an interested organization
- Activities for government or non-profit agencies

These disclosures are required annually on a rolling basis

\* *Significant Financial Interests*

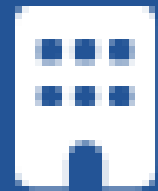




# Conflicts in Sponsored Research

Presumption: Covered Individuals who have a financial Interest above the de minimis threshold in a business may not receive sponsored research support from that business.

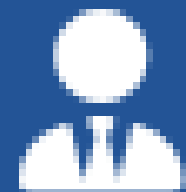
The relevant de minimis thresholds are:



1. Any type of ownership interest in a privately held business



2. >1% equity stake in a publicly traded Business
  - a. A lower equity stake is not excluded from consideration if:



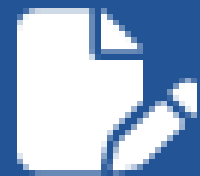
- i. The business was founded by the individual, or
    - ii. The equity was acquired in connection with the research at issue.





# Overcoming COI Presumption

To request an exception to our COI policy, a Covered Individual must:



1. Complete the Sponsored Research Exception Request Form



2. Submit it to the Conflicts Review Officer to initiate the review process

The presumption may be overcome when it is determined the benefits of the proposed research outweigh the risks; the related interest must be able to be appropriately managed.



# Detecting Conflicts with External Engagements

Reviewing consulting agreements:

- a. Policy Overview
  - i. Covered Individuals
  - ii. Permitted & Prohibited Activities
  - iii. Discussion with Supervisor
- b. Process
  - i. Draft
  - ii. Submission
  - iii. Agreement Review
  - iv. COI Committee Review
  - v. Determination
- c. Screening Parties
  - i. Entity
  - ii. Contacts



# Annual Meetings

- Generally reserved for those with a management plan
- ✓ ◦ Individuals with external engagements that create potential or actual conflicts of interest
- Cross-functional participation
- ✓ ◦ Animal research/ use, sponsored research, conflicts
- Dissemination and receipt of important information
- ✓ ◦ Policy updates, upcoming external activities



# Conflicts of Commitment

Two main areas of concern:

1. Commitment of time to external engagements; (“basic” COC - time)
  - a. 20% effort cap
2. Malign Foreign Talent Recruitment Programs (MFTRP)
  - a. NSPM-33
    - i. A situation in which an individual accepts or incurs conflicting obligations between or among multiple employers or other entities.
      - Broadly includes: ex. obligations to share improperly information with, or to withhold information from, an employer or funding agency.



# CHIPS and Science Act

Each federal research agency shall establish a policy that, as part of a proposal for a research and development award from the agency:

- Each covered individual listed in such proposal certify that they are not a party to a MFTRP; and
- Each organization applying for such an award certify that each covered individual has been made aware of related requirements







# Defining a FTRP

Any program, position, or activity that includes compensation provided by a foreign country or their designee, or an entity based in, funded by, or affiliated with a foreign country to an individual.



# Defining a MFTRP

A MFTRP is a FTRP that involves compensation in exchange for:

-  • Participating in the transfer of intellectual property, materials, data, or other nonpublic information
-  • Recruiting other individuals to enroll in a MFTRP
-  • Establishing a laboratory or company or accepting a faculty position or other employment in a foreign country in violation of T&C of a Federal research award
-  • Limiting an individual's ability to engage in a research and development award

Also, any program sponsored by a foreign country of concern (FCOC), any entity based in a FCOC, or any other entity as designed by applicable laws and government entities.



# MFTRP Restrictions

- National Science Foundation: Individuals who are a current party to a MFTRP)are not eligible to serve as a senior/ key person on an NSF proposal or on any NSF award made after 5/20/24.
- National Institutes of Health: Effective 9/ 11/ 25, individuals who are a current party to a MFTRP are not eligible to serve as a senior/ key person on an NIH grant or cooperative agreement.
  - (*rescinded*)
- Attestations:
  - Language:
    - “I also certify that, at the time of submission, I am not a party in a malign foreign talent recruitment program.”
  - Timing
    - Prior to submission/application
    - Annually thereafter





# Examples/Case Studies

**Former West Virginia University professor sentenced for fraud that enabled him to participate in the People's Republic of China's "Thousand Talents Plan"**

**Harvard University Professor and Two Chinese Nationals Charged in Three Separate China Related Cases**



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# QUESTIONS

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