

# Identifying and Managing Conflicts of Interest in Human Subjects Research

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# Outline

- What is a conflict of interest?
- Where does COI policy come from?
- What does Northwestern COI policy require?
- How do research reviews work in IRB studies?

# What is a Conflict of Interest?

A conflict of interest is a situation in which an individual's **financial, professional, or other personal considerations** have the potential to affect, or have the appearance of affecting, their **professional judgment**.

**Financial Conflict of Interest** exists when institutions with which the individual is affiliated, through its designated official(s), reasonably determines that an Investigator's **Financial Interest** is related to a funded research project and could directly and significantly affect the **design, conduct or reporting of the funded research**, or present the appearance thereof.

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*"Try this—I just bought a hundred shares."*

# What a Conflict of Interest is Not

- A conflict of interest is a **situation** that introduces an **opportunity** for bias, but it is not a guarantee, or even a likelihood of bias
- A conflict of interest does not qualify as research misconduct
- A conflict of interest is **not necessarily a bad thing**
- It is very hard to identify and regulate bias. The closest we can come is minimizing the **opportunity** for bias to be introduced.

# Historical Cases

## Jesse Gelsinger and Dr. James Wilson

- Gene therapy study at University of Pennsylvania
- Jesse Gelsinger died as a result of the study
- Dr. Wilson had **undisclosed** financial interest in the therapy under study
- Investigation revealed that the PI had a start-up company formed around gene therapy; University of Pennsylvania was an investor in the company

# Dr. Charles Nemeroff

- Psychiatrist at Emory University
- **Failed to report** to the university \$1.2M in payments from pharma companies
- Example: Agreed to limit compensation to \$10,000 per year from GSK; actually earned \$170,000 in a year.
- Relationships were unmanaged or not properly managed due to Nemeroff's failure to disclose

# Senator Grassley's Investigation

Senator Charles Grassley (R. Iowa) led Congressional inquiries from 2004 – 2010 comparing conflict of interest disclosures from researchers to records of actual payments from drug companies.

## Sunshine Act/Open Payments Act

- Passed as part of the 2010 Affordable Care Act
- Requires pharmaceutical/medical device companies to make payments to physicians publicly available
- Searchable, exportable database of payments from pharma to doctors (<https://openpaymentsdata.cms.gov/>)

<https://www.sciencedirect.com/science/article/abs/pii/S0160252712000726>

# 2012 Update to Public Health Service Act

- 42 CFR Part 50 Subpart F was originally adopted in 1995
- It contains COI regulations that we base our COI policies on
- In 2012 Health and Human Services (HHS) updated COI regulations. Updates are called “Final Rules.”

# What Changed with the 2012 Final Rule?

## 1995 Regulations

- Investigators self-report: they must disclose financial interests that they determine could be a COI
- \$10,000 disclosure threshold
- No obligation to report travel
- No obligation for public reporting
- No training requirement

## 2012 Regulations (Final Rule)

# 2021 – present; COI and other agencies

- 2021 - Department of Energy released an interim COI policy and requirements.
- 2024 - Department of Defense updated a risk assessment and requirements for institutional review of potential conflicts of interest and commitment.
- 2023 - NSF added disclosure requirement for other investors in startups.
- NASA released new requirements for COI & COC, went into effect December 2023.

# Northwestern COI in Research Policy Highlights

- **Covers** anyone involved in federal, industry, or other sponsored research with sponsor COI requirements; covers all human subjects research
- Requires **COI training**
- Requires **disclosure** of significant financial interests (SFIs) annually and within 30 days of acquiring a new interest
- Provides detailed definition of what an SFIs
- **Mandates review** of SFIs by NUCOI and school dean's offices prior to expenditure of funds
- Defines and prohibits participation on **malign foreign talent recruitment programs**
- Explains **management plans** and **reporting requirements**

[https://www.northwestern.edu/coi/policy/research\\_policy.pdf](https://www.northwestern.edu/coi/policy/research_policy.pdf)

# Northwestern's COI Process



Investigators disclose external interests and relationships



Northwestern reviews interests and research to identify COIs



Elimination, reduction, or management of COIs



Monitoring compliance with management strategies

# Policy & Disclosure Requirements

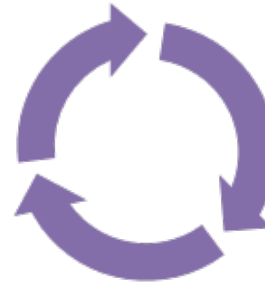
## Annual Disclosure Process

Policy on Conflict of Interest and Conflict of Commitment

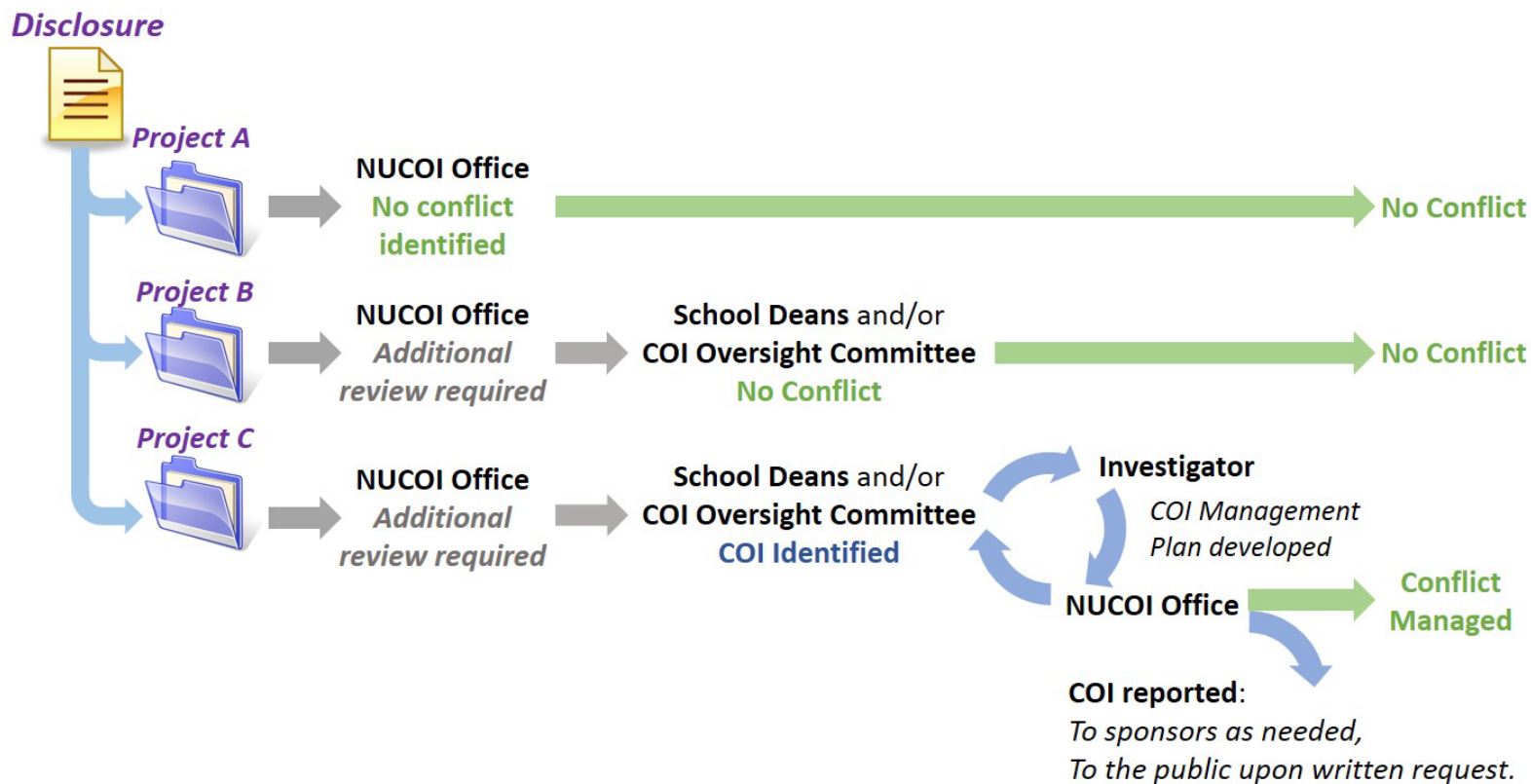


## Research Process

Policy on Conflict of Interest in Research



# Northwestern's COI Review Process



# Some Metrics

NUCOI does **~6.5-7K research reviews** per year.  
We send **~250 for school review** per year.  
Of those, **~85%** end up with management.

Steady state is **~950 research projects under COI management** at any given time.  
Of these **~775 are IRB protocols**.  
**10-15%** are NIH funded.

# Factors considered in COI reviews



## Nature, Extent, Relatedness

- External consulting
- Start-up companies
- Equity interests
- Option or licensing activity
- Intellectual property interests and stage
- Nature of research
- Role

# Management Plans & Strategies

Management strategies may include:

- Disclosure / transparency:
  - To research team & collaborators
  - In presentations & publications
  - In **informed consent forms**
- Keep outside activities separate from Northwestern activities. Unless there is an agreement in place, avoid:
  - Involving students & others in outside activities / personal financial interests
  - Using Northwestern resources (space, equipment) in outside work
- Recusal from negotiations between Northwestern & entity
- Independent reviews of research/other data/results
- Reduced role in research

# When do Research Reviews Happen?

- When new awards are received by SR, NUCOI is notified by CERES ancillary review
- NUCOI runs reports to identify **IRB new studies** twice a week (the report is our “dashboard”)
  - IRB Panel approval is held until all investigators are clear for COI
  - For approved studies, review is needed for changes in PI and/or changes in SFIs
- When investigators update their disclosure, NUCOI reviews the disclosure and may or may not review all existing research projects

# How Do I know the COI status of my investigators?

Look at the COI tab in eIRB+ or CERES



History	Funding	Project Contacts	Documents	IRB Assignment Details	Reviews	Study Team Training	Snapshots	COI	COI Mgmt Plans
Research Project ID: [REDACTED] (Active)									
Research Project Name: [REDACTED]									
COI Discloser	COI Training Date	Last Submitted Disclosure		Role on Study		COI Determination			
[REDACTED]	2/14/2025	2/14/2025		Principal Investigator		No Conflict			

eIRB+

CERES

Totals	Funding Allocations	Deliverables	Subawards	Child Awards	Related Projects	COI Status	...
NU Personnel							
PI First Name	PI Last Name	Last Disclosure Update Date	COI Training Completion Date		COI Review Status		
[REDACTED]	[REDACTED]	2/3/2025	2/3/2025		Under Review		
First Name	Last Name	Last Disclosure Update Date	COI Training Completion Date		COI Review Status		
[REDACTED]	[REDACTED]	2/25/2025	2/25/2025		No Conflict		
1 items		◀ page 1 of 1 ▶			10 / page		
Non-NU Personnel							
Full Name	Subrecipient Org	Last Disclosure Update Date	COI Training Completion Date		COI Review Status		
[REDACTED]	[REDACTED]	8/20/2024	8/20/2024		Under Review		
[REDACTED]	[REDACTED]				Under Review		

# What if there are external investigators?

- Subawards to institutions that have PHS-compliant COI policies *do their own reviews*
- Subs to institutions that **do not** have PHS-compliant COI policies must be covered by Northwestern's COI policy and their investigators disclose to Northwestern
- Faculty from compliant institutions who are acting as *individual consultants* must be covered by Northwestern's COI policy

# What else does NUCOI do?

## Conflict of Commitment

- Faculty and staff owe their primary professional allegiance to Northwestern. A conflict of commitment occurs when time devoted to outside activities adversely affects capacity to meet University responsibilities.
- Faculty and staff intending to engage in external activities that involve significant effort need prior approval.

## COI for Purchasing

- Faculty and staff cannot direct the purchase of goods and services from entities in which they or their relatives have a financial interest

## Assist in Research Security Functions

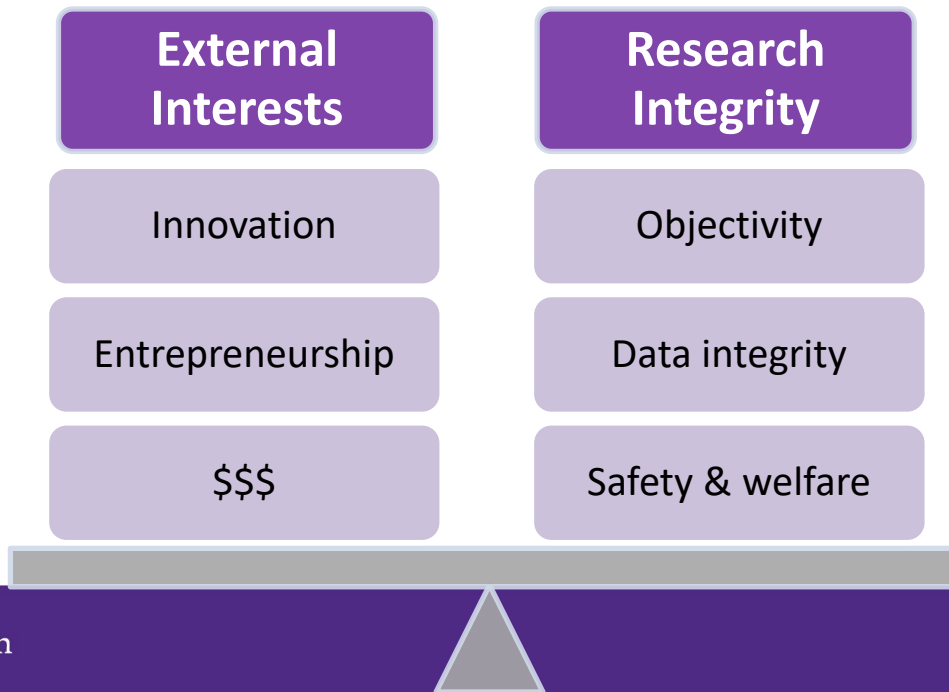
- Certify on malign foreign talent recruitment participation and help screen for high-risk activities

# Summary

Ultimately, COI management is about mitigating the risk that an individual's external financial interests may bias or compromise

– or have the *appearance* of biasing or compromising –

an individual's judgment, objectivity, or decision-making in research



# Contact Information

## NUCOI Team

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Questions?

# Key COI Resources

**Northwestern Conflict of Interest Office (NUCOI):**

<http://www.northwestern.edu/coi/>

**eDisclosure:** <https://coi.northwestern.edu>

**COI in Research Policy:**

[http://www.northwestern.edu/coi/policy/research\\_policy.pdf](http://www.northwestern.edu/coi/policy/research_policy.pdf)

**One-Page Guide on Research COI Process for Investigators and Administrators:**

[https://www.northwestern.edu/coi/docs/one-pager-research-disclosure\\_vfinal.pdf](https://www.northwestern.edu/coi/docs/one-pager-research-disclosure_vfinal.pdf)

**Guidance for Investigators under COI Management; Examples of Disclosure Language:**

<https://www.northwestern.edu/coi/management-plans/example-language.html>

# Research Compliance: Policies

- Northwestern University has in place a number of policies that demonstrate our commitment to research integrity.
  - [Faculty Handbook](#)
  - [Northwestern Standards for Business Conduct](#)
- Key policies for faculty:
  - [Export Controls Compliance](#) – Amy Weber, Export Controls
  - [Patent and Invention](#) – Lisa Dhar, INVO
  - [Research Data: Ownership, Retention and Access](#) – SR & ORI
  - [Research Misconduct](#) – Lauran Qualkenbush, ORI
    - *Note:* Northwestern defines “Research Misconduct” as:
      - Falsification, Fabrication, Plagiarism, and
      - Serious deviations from accepted research practices including misuse of confidential information gained through peer review