

# 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

## 2012 Regulations (Final Rule)

- \$10,000 disclosure threshold
- No obligation to report travel
- No obligation for public reporting
- No training requirement

# 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

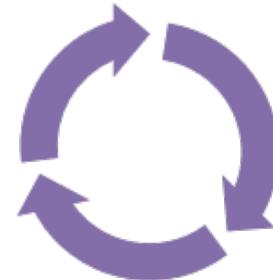
# Policy & Disclosure Requirements

Policy on Conflict of  
Interest and Conflict  
of Commitment

Annual  
Disclosure Process

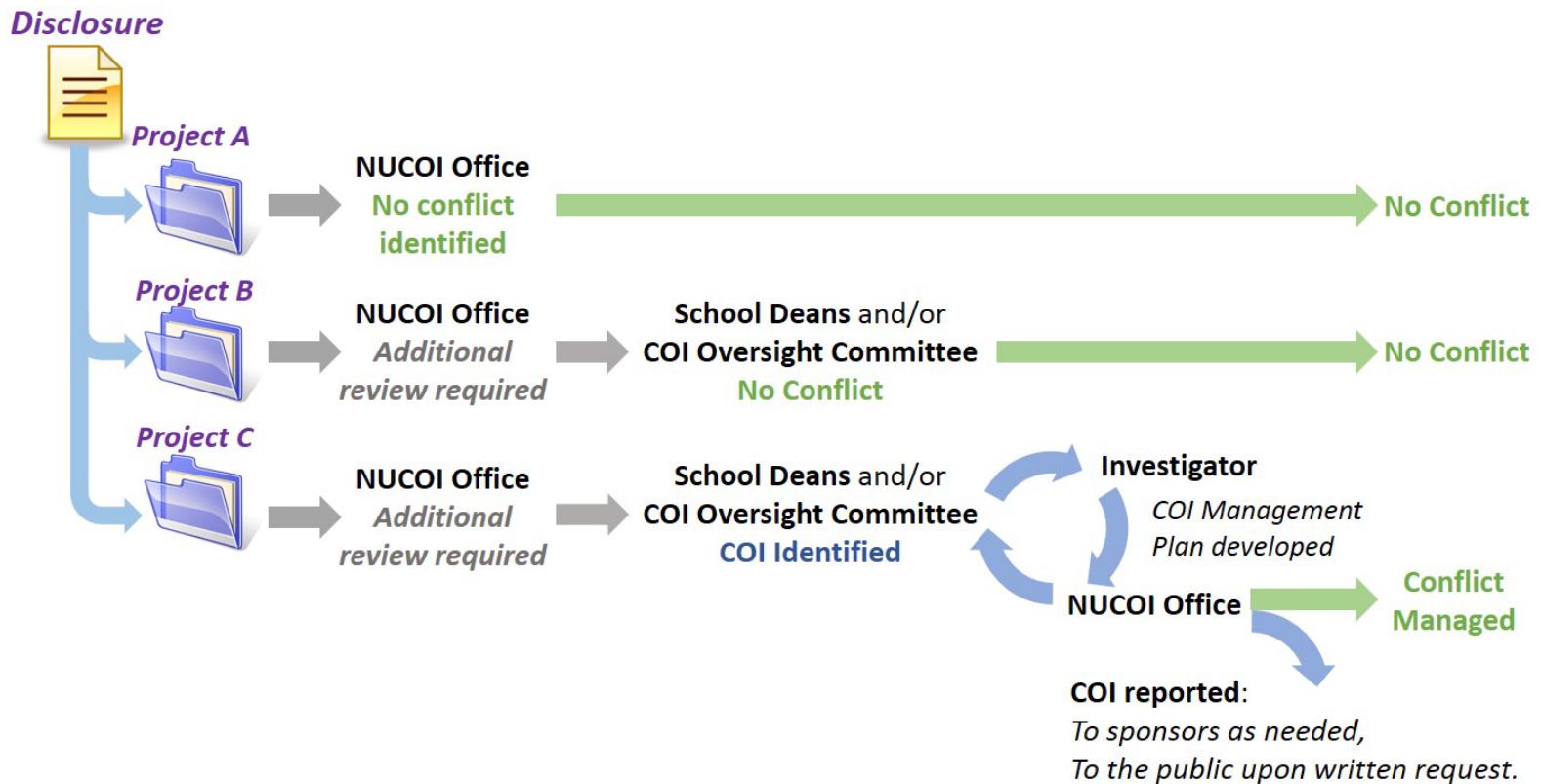


Research Process



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
<b>Research Project ID:</b> [REDACTED] (Active)									
<b>Research Project Name:</b> [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	...			
<b>NU Personnel</b>										
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 <input type="text" value="1"/> of 1 ▶		<input type="text" value="10"/> / page						
<b>Non-NU Personnel</b>										
		Last Disclosure Update Date	COI Training Completion Date	COI Review Status						
[REDACTED]		8/20/2024	8/20/2024	Under Review						
[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

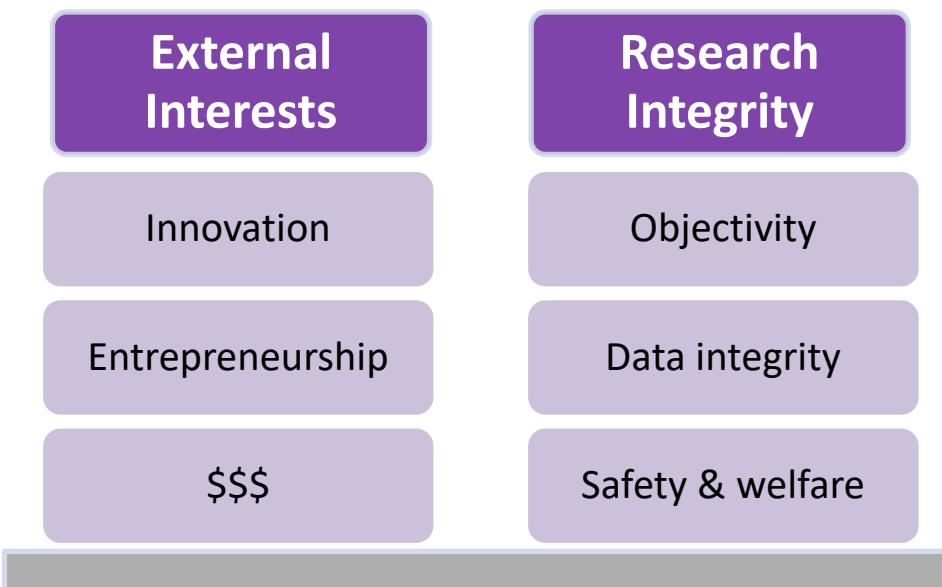
- Certify on malign foreign talent recruitment participation and help screen for high-risk activities

# 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