

Research Conflict of Interest (COI) Training Module

February 2025

Northwestern | CONFLICT OF INTEREST

Learning Objectives

At the end of this training module, you will understand:

- The federal COI and Conflict of Commitment (COC) requirements that guide Northwestern's research policy and processes
- Who is subject to research COI and COC requirements
- The term **“Significant Financial Interest” (SFI)**
 - Where and when SFIs must be disclosed
 - How SFIs are reviewed at Northwestern
- The term **“Financial Conflict of Interest” (FCOI)**
 - How FCOIs are managed
 - How FCOIs may be reported to sponsors and to the public
- Implications for noncompliance with research COI and COC requirements

Why do we care about COI in research?

As a condition of federal funding, the University must establish procedures 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 (FCOIs)**.

Federal regulations require that the University:

1. Maintain a current, documented, and enforced COI and COC policy
2. Educate Investigators as to Northwestern's policies and procedures
3. Facilitate and ensure Investigator compliance with initial and ongoing disclosure requirements
4. Identify and manage FCOIs
5. Flow down sponsor COI and COC requirements to subrecipients
6. Meet sponsor and other COI and COC reporting requirements

Key Aspects of NU's COI Requirements

- **Investigators** must disclose all SFIs and other **professional activities** related to their institutional responsibilities within 30 days of acquiring or becoming aware of a new interest and at least annually.
 - Given you are receiving this training, you meet the criteria of Investigator and are subject to all Investigator requirements.
- **Institutions** review disclosures and determine whether an SFI could be an FCOI for each research activity in which an Investigator is involved.
- **Institutions** must eliminate, reduce, or manage FCOIs, mitigate other potential conflicts, and meet sponsor and other FCOI reporting requirements.

Who and What is Subject to Research COI Requirements?

- Investigators and Covered Individuals* who
 - Submit applications for research funding to any federal or industry sponsors, or other sponsors that have conflict of interest requirements, and/or
 - Are engaged in research involving human research participants subject to review by Northwestern's Institutional Review Board (IRB) or an external IRB (as defined in any reliance agreement), regardless of funding source.
- Proposals submitted to/research funded by:
 - Federal sponsors
 - Industry sponsors
 - Other sponsors that have specific COI terms and conditions
- All research involving human participants regardless of funding source

** See the Conflict of Interest in Research policy for the full definition of an Investigator and a Covered Individual*

What Must Be Disclosed? – Financial Interests

Nature of SFI	Threshold/Description*
Compensation and/or other payments for service	Exceeding \$5,000 (from one entity in the 12 months prior to disclosure date)
Equity interests in a publicly-traded entity	Exceeding \$5,000 (from one entity in the 12 months prior to disclosure date)
Equity or other ownership interests in a non-publicly-traded entity (e.g., startup companies)	\$0 value / Any ownership interest (i.e., ANY and ALL equity interests in non-publicly traded entities – including founders shares)
Intellectual property rights and interests upon receipt of income related to such rights and interests (e.g., royalties)	Exceeding \$5,000 (from one entity in the 12 months prior to disclosure date)
Sponsored or reimbursed travel <i>Applies to <u>PHS-funded researchers only</u>: Investigators who have any PHS funding or any funding from agencies following PHS COI regulations must disclose any reimbursed or sponsored travel</i>	Exceeding \$5,000 (from one entity in the 12 months prior to disclosure date)

*There is a \$0 threshold for the Feinberg School of Medicine

What Does NOT Need to be Disclosed?

Nature of Interest	EXCLUDED FROM DISCLOSURE: DO NOT DISCLOSE
General	<ul style="list-style-type: none"> Anything (compensation, equity, royalties, or travel) that does not meet the disclosure threshold
Compensation and/or other payments for service	<ul style="list-style-type: none"> Any compensation received for lectures, seminars, or service on advisory committees or review panels relating to U.S. federal, state, or local government agencies, a U.S. institution of higher education as defined in 20 U.S.C. 1001(a), a U.S. academic teaching hospital, medical center, or a research institute that is affiliated with a U.S. institution of higher education, and/or compensation received from or through Northwestern funds
Equity interests	<ul style="list-style-type: none"> Interests in any entity through personal retirement accounts, mutual funds (403b, IRA, etc.), or other funds that are managed by a third party with discretion
Certain IP rights and interests	<ul style="list-style-type: none"> Royalties received from Northwestern funds, and unlicensed intellectual property that does not generate income
Sponsored or reimbursed travel <i>Applies to PHS-funded researchers only: Investigators who have any PHS funding or any funding from agencies following PHS COI regulations must disclose reimbursed or sponsored travel</i>	<ul style="list-style-type: none"> Travel administered through Northwestern funds, and travel reimbursed or sponsored by a U.S. federal, state, or local government agency, a U.S. institution of higher education, a U.S. academic teaching hospital, medical center, or a research institute that is affiliated with a U.S. institution of higher education.

What Must Be Disclosed? – Other Activities

In addition to SFI-related disclosures, Northwestern researchers may be asked to disclose other activities, including

- Involvement of Northwestern students, postdoc, and staff in external activities
- Teaching or research with an external organization
- Certain fiduciary relationships (e.g., board positions)
- Participation in any foreign talent recruitment program*
- Other school-specific questions, as applicable

* Participation in a [Malign Foreign Talent Recruitment Program](#) is prohibited for researchers applying for or receiving federal funding. The Office of Export Controls and International Compliance may be consulted on disclosed relationships with foreign entities.

Factors to Consider regarding Relationships with Foreign Entities

Do you have a relationship with, or funding from, a foreign country where activities include recruitment of scientists?

Does the relationship involve any kind of compensation (monetary or non including honorific titles and future compensation)?

If you respond “**yes**” to **any** of these questions,

Disclose this relationship.

Provide details in your answer to the question about foreign talent recruitment programs.

Is the country China, Iran, Russian or North Korea? **AND**

Does the relationship require **any** of the following?

- Recruit others (trainees, researchers, speakers, etc.) to participate in a talent program with a foreign entity
- Hold a position, laboratory, or company in a foreign country
- Engage in a contract/agreement where termination is not an option or is difficult
- Transfer IP (intellectual property), materials, data, or other nonpublic information
- Engage in work for or in another country that overlaps with U.S. federal dollars
- Apply for or receive funding from a sponsoring foreign entity without engaging Sponsored Research
- Omit a recipient affiliation, or being told/required to make omissions
- Conceal program participation in any way

If so, **in addition to disclosing the relationship**, consult with your dean’s office **and** the Export Controls and International Compliance team to assess whether this program may be considered a “malign” foreign talent recruitment program: exportcontrols@northwestern.edu.

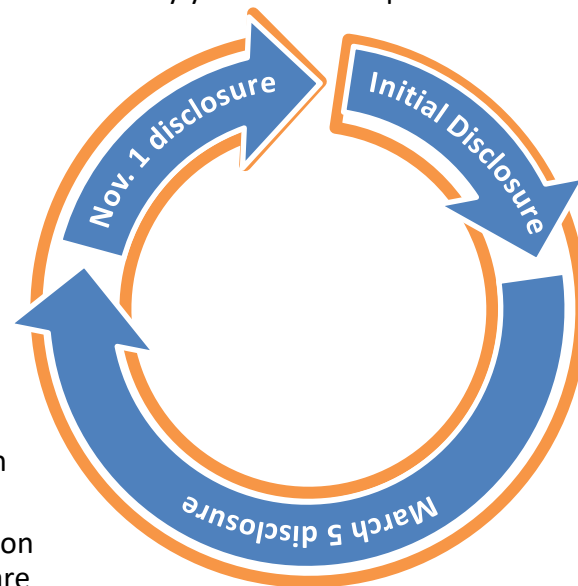
When do Investigators Need to Disclose?

- Before engaging in research
 - A disclosure must be on file in eDisclosure for each Investigator on a proposal **before:**
 - The proposal can be submitted to the sponsor by the institution, and/or
 - An IRB protocol can be approved by Northwestern's Institutional Review Board (IRB).
- Within 30 days of receiving or becoming aware of a new SFI
 - SFIs must be disclosed in eDisclosure within 30 days of acquisition, receipt of payment, etc.
 - Do **NOT** wait until annual disclosure time to update your disclosure with new SFIs.
- At least annually
 - If you have no new SFIs to disclose between annual COI disclosure cycles, the annual COI disclosure is sufficient. You must complete a COI disclosure annually, even if acknowledging no change.

Example Investigator's Yearly Disclosures

Annual Disclosure in February:

If you have no new SFIs through the year, the Annual Faculty/Staff COI process will satisfy your annual requirement.



November 1: Received \$6000 consulting fee from BioOptical Experts, LLC

✓ **Do** disclose remuneration; exceeds \$5,000 disclosure threshold

September: Received an honorarium from Stanford for a talk.

Do **not** disclose; Stanford is a U.S. institution of higher education; one-time honoraria are exempt from disclosure

June: Received a royalty payment from Northwestern for a device

Do **not** disclose; payments through Northwestern do not need to be disclosed

March 5: Incorporate start-up company; Role = founder/owner; Value = \$0

✓ **Do** disclose new equity/ownership

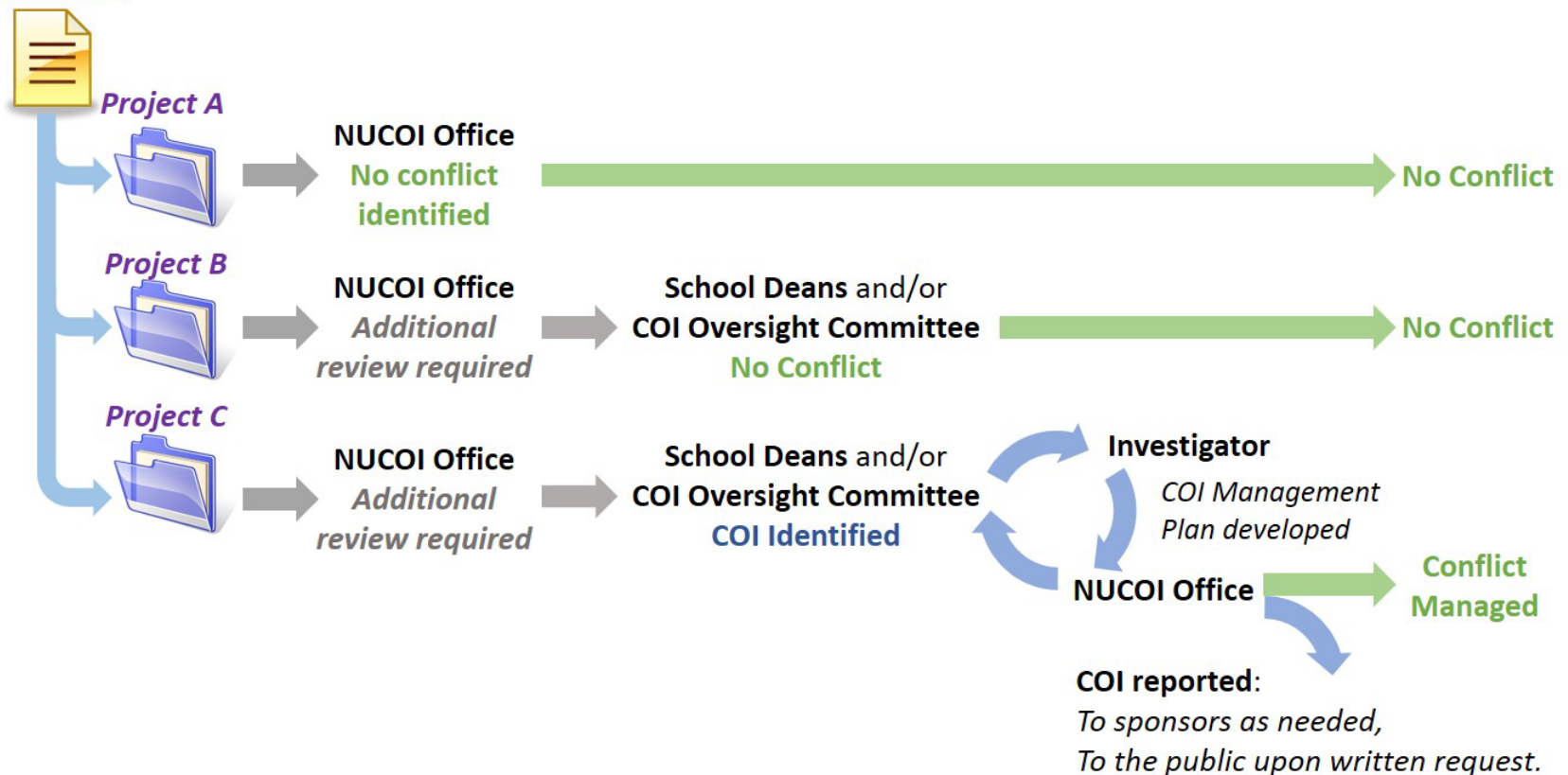
April: Received \$3500 speakers fee and \$1000 in reimbursed travel from Takeda Pharmaceuticals

Do **not** disclose; does not meet \$5000 threshold

How Are Disclosures Reviewed?

Research projects are reviewed with regard to the nature, extent, and relatedness of disclosed financial interests. NUCOI performs an initial review; potential financial COIs are referred to school-based reviewers or committees for a final determination.

Disclosure



How Are Disclosures Reviewed

Disclosures are reviewed comprehensively with regard to

- Potential conflicts of commitment
- Relationships with foreign entities that could potentially impact federal funding

What Happens if an FCOI is Identified?

If an FCOI is identified, the School COI representative(s) and NUCOI will work with the Investigator to **reduce, manage, or eliminate** the COI.

- Examples of management strategies include:
 - Disclosure in publications
 - Disclosure to colleagues and collaborators
 - Disclosure to IRB and to research participants
 - Reduced role in project
 - Independent data review and/or monitoring

Some sponsors require that certain information relative to FCOIs be reported prior to expenditure of funds, which is done by the NUCOI office. NUCOI notifies Investigators prior to such reporting.

Certain FCOI information relative to PHS-funded research must be made available to the public upon request. NUCOI notifies Investigators prior to provision of such information.

What is Considered Noncompliance Relative to COI?

Noncompliance includes **failure to disclose, identify, review, or manage COIs** as required by federal regulations and University policy. The following are considered instances of Investigator noncompliance:

- Failure to disclose information as required
- Failure to submit an updated disclosure within 30 days of acquiring a new SFI
- Submission of an incomplete, erroneous, or misleading initial, updated or annual disclosure
- Failure to comply with COI management plan strategies established by the University

Instances of non-compliance will be reviewed and disciplinary action taken, if needed, in accordance with applicable University policies and procedures.

Relative to PHS, NASA, and DOE-funded research, noncompliance may result in the need for Northwestern to perform a federally-required retrospective review of the Investigator's activities and the applicable research project(s) to determine whether any applicable research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.

What is a Conflict of Commitment?

Faculty and staff owe their primary professional commitment of time and intellectual energies to education, research, and other programs supporting Northwestern's mission. A Conflict of Commitment occurs when a faculty or staff member's time devoted to outside activities adversely affects their capacity to meet University responsibilities.

- The [Faculty Handbook](#) describes expectations for faculty.
- The [Staff Handbook](#) describes expectations for staff.
- Faculty and staff are subject to the University's [Patent and Invention Policy](#).
- Engagement in an external activity that involves significant effort outside the University must have advanced written approval from the relevant department chair and dean/unit head.

Questions? Concerns? Guidance?

Contact Northwestern's Conflict of Interest Office (NUCOI)

Email: nucoi@northwestern.edu

Phone: (847) 467-4515

Northwestern's COI In Research Policy is available here:

http://www.northwestern.edu/coi/policy/research_policy.pdf

Complete Training

- ✓ Please return to eDisclosure to **Attest** to having reviewed this training by clicking the attestation checkbox on the training page.
- ✓ Then, navigate through the disclosure form in eDisclosure by clicking the “Continue” button to complete and submit your disclosure.

Thank you!