Learning Objectives

At the end of this training module, you will:

• Understand the federal COI requirements that guide the University’s research COI policy and processes
• Understand who is subject to research COI requirements
• Understand what is encompassed in the term “Significant Financial Interest” (SFI)
• Understand where and when SFIs must be disclosed
• Understand how SFIs are reviewed at Northwestern
• Understand the term “Financial Conflict of Interest “ (FCOI)
• Understand how FCOIs are managed
• Understand how FCOIs may be reported to sponsors and to the public
• Understand implications for noncompliance with research COI requirements
Why do we care about COI in Research?

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 with respect to research design, conduct, or reporting.

The relation - even potential or perceived relation - of external interests to research integrity needs to be assessed.
Conflicts of Interest in Research

Common sources for COIs: invention licensing, faculty start-up companies, consulting relationships, etc.

Considerations of personal financial gain must not influence the decisions or actions of individuals in carrying out their University responsibilities and research. The perception that such incentives might harm research objectivity or the protection of human subjects, students or others whose work depends on the direction of the Investigator, is enough to mandate that such conflicts be identified, and then managed, reduced or eliminated.
What Must Northwestern Do to Comply?

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 {or COIs*})

Federal regulations require that the University:

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

* We use the general term “COI” across the board to avoid confusion among various sponsors’ vernacular when it comes to COI terminology
Key Aspects of NU’s COI Requirements

• Investigators must complete COI training prior to engaging in research and every four years, and more frequently as needed (e.g., non-compliance)

• Investigators must disclose all SFIs related to their Institutional Responsibilities (not just outside interests they judge to relate to particular research activity) on an ongoing basis

• Institutions determine whether an SFI could be an FCOI for each body of research activity in which an Investigator is involved

• Institutions must eliminate, reduce, or manage FCOIs, and meet sponsor and other FCOI reporting requirements

Please familiarize yourself with Northwestern’s COI In Research Policy, available here: http://www.northwestern.edu/coi/policy/research_policy.pdf
Research Sponsors Encompassed in NU’s COI Requirements

All federal and industry sponsors, including, but not limited to:
- National Institutes of Health
- National Science Foundation
- Agency for Healthcare Research and Quality
- Centers for Disease Control and Prevention
- US Food and Drug Administration
- Department of Defense
- Department of Energy
- Environmental Protection Agency

All research involving human research participants, regardless of funding source

Other sponsors with specific COI requirements

Sponsors specifically known to abide by the PHS Regulations, including:
- American Heart Association
- American Cancer Society
- Alliance for Lupus Research
- Arthritis Foundation
- American Lung Association
- California Breast Cancer Research Program
- California HIV/AIDS Research Program
- CurePSP (Society for Progressive Supranuclear Palsy)
- Juvenile Diabetes Research Foundation (JDRF)
- Lupus Foundation of America
- PCORI
- Susan G Komen Foundation
Who is Subject to Research COI Requirements?

**Investigators**, defined as:

*Any person, regardless of title or position, who is responsible for the design, conduct or reporting of research*

- This **always** includes:
  - Project Director / Principal Investigator
  - Anyone named as Key Personnel (by virtue of the definition of Key Personnel*)
- This **may also** include (upon PI decision):
  - Outside collaborators (e.g., subrecipient Investigators, consultants) who satisfy the definition of being responsible for the design, conduct, or reporting of the research
  - Any other faculty, staff, post-doctoral and clinical fellows, graduate students, or even technicians, who satisfy the definition of being responsible for the design, conduct, or reporting of the research

- **Anyone named as a PI or co-I on a protocol for research with human participants submitted to Northwestern’s IRB**

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*Key Personnel: an individual who contributes in a substantial and measureable way to a project. Therefore, someone meeting this definition would most certainly be an Investigator (someone responsible for the design, conduct, or reporting of research)*

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**For example:**

Sally, the technician is probably **not an investigator** if she:

- Follows recipes to make solutions,
- Feeds the mice and performs husbandry, or
- Maintains equipment through routine maintenance.

Sally probably **would be considered an investigator** if she:

- Independently optimizes a solution for improved antibody staining,
- Pioneers / develops a new strain of mice with a new reporter gene, or
- Alters / improves equipment to have better detection limits.
Where do Investigators Disclose?

All Investigators disclose in eDisclosure, including:
- Northwestern Investigators
- Individuals named as PIs or co-Is on IRB protocols submitted to Northwestern’s IRB
- Subrecipient Investigators (only if following Northwestern’s policy)
- Consultants (only if meeting the definition of “Investigator” per the project PI)
What Must Be Disclosed?

Significant Financial Interests related to an Investigator’s Institutional Responsibilities

**Significant Financial Interests** (definition detailed on next slide) held by an Investigator, or an Investigator’s Immediate Family Members, that is reasonably related to their University responsibilities

**Immediate Family Members** include: spouse, dependent children, and/or domestic or civil union partner

**University Responsibilities** refer to an Investigator’s professional responsibilities performed on behalf of Northwestern University, which may include activities such as:

- Research
- Research consultation
- Teaching and advising
- Institutional committee memberships and other service
- Service on institutional panels
## What Must Be Disclosed?

<table>
<thead>
<tr>
<th>Nature of SFI</th>
<th>Threshold/Description</th>
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<tbody>
<tr>
<td><strong>Compensation and/or other payments for service</strong></td>
<td>Exceeding $5,000* (from one entity in the 12 months prior to disclosure date)</td>
</tr>
<tr>
<td><strong>Equity interests in a publicly-traded entity</strong></td>
<td>Exceeding $5,000 (from one entity in the 12 months prior to disclosure date)</td>
</tr>
<tr>
<td><strong>Equity or other ownership interests in a non-publicly-traded entity</strong></td>
<td>$0 value / Any ownership interest (i.e., ANY and ALL equity interests in non-publicly traded entities)</td>
</tr>
<tr>
<td><strong>Intellectual property rights and interests upon receipt of income related to such rights and interests (e.g., royalties)</strong></td>
<td>Exceeding $5,000* (from one entity in the 12 months prior to disclosure date)</td>
</tr>
<tr>
<td><strong>Sponsored or reimbursed travel</strong></td>
<td>Exceeding $5,000 (from one entity in the 12 months prior to disclosure date)</td>
</tr>
</tbody>
</table>

*Faculty with primary appointments in FSM have an are subject to a zero dollar disclosure threshold for remuneration and intellectual property interests. Please read each question in eDisclosure carefully.*
## What Does NOT Need to be Disclosed?

<table>
<thead>
<tr>
<th>Nature of Interest</th>
<th>EXCLUDED FROM DISCLOSURE: DO NOT DISCLOSE</th>
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</table>
| **General**        | • Anything unrelated to one’s Institutional Responsibilities (e.g., you are an engineering faculty member and have stock interests in Starbucks, which in no way relates to your field of study or research)  
                     • Anything (compensation, equity, royalties, or travel) that does not meet the disclosure threshold  
                        • E.g., Non-FSM faculty, should not disclose remuneration that does not exceed $5,000 from one entity in the 12 months previous to disclosure date |
| **Compensation and/or other payments for service** | • Any compensation received for lectures, seminars, teaching engagements, or service on advisory committees or review panels relating to federal, state, or local government agencies, an institution of higher education as defined in 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, and/or compensation received from or through NU funds |
| **Equity interests** | • Interests in any entity through personal retirement accounts and mutual funds (403b, IRA, etc.) |
| **Intellectual property rights and interests** | • Royalties received from NU funds, and unlicensed intellectual property that does not generate income |
| **Sponsored or reimbursed travel** | • Travel administered through NU funds, and travel reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.  
  *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* |
When do Investigators Need to Disclose?

• **Before engaging in research proposed to or funded by sponsors subject to Northwestern’s COI requirements**
  – A disclosure must be on file in eDisclosure for each Investigator on a proposal **before** the proposal can be submitted to the sponsor

• **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 the next annual disclosure time to update your disclosure for new SFIs that arise subsequent to the annual disclosure period

• **At least annually**
  – If you have no new SFIs to disclose between annual faculty/staff disclosure cycles, the annual disclosure is sufficient. You must complete a disclosure annually, even if acknowledging no change
Ongoing Disclosure Requirements

Disclose **new SFIs within 30 days** of acquiring or becoming aware of them, and **at least annually**.

- **Annual Disclosure in February:**
  If you have no new SFIs that arise through the year, the annual Faculty/Staff disclosure process will satisfy your annual requirement.

- **November 1:** Received $6000 consulting fee from BioOptical Experts, LLC
  - **Do** disclose remuneration; exceeds $5,000 disclosure threshold (disclose by 12/1)

- **March 5:** Incorporate start-up company; Role = founder / owner; Value = $0
  - **Do** disclose new equity/ownership (disclose by 4/5)

- **April 15:** Received $3500 speakers fee and $1000 in reimbursed travel from Takeda Pharmaceuticals
  - Do **not** disclose; does not meet $5000 threshold
  - *If a Feinberg faculty member, do disclose the speakers fee as the FSM threshold for remuneration is $0 (disclose by 4/15)*

- **September 1:** Received an honorarium from Stanford for a talk.
  - Do **not** disclose; Stanford is an institution of higher education institution and thus exempt from disclosure

- **June 1:** Received a royalty payment from Northwestern for a device
  - Do **not** disclose; payments through Northwestern do not need to be disclosed

- **November 1:** Received $6000 consulting fee from BioOptical Experts, LLC
  - **Do** disclose remuneration; exceeds $5,000 disclosure threshold (disclose by 12/1)
How Are Disclosures Reviewed?

Disclosures/SFIs are reviewed in comparison to each research project subject to Northwestern’s COI requirements. NU COIO performs an initial review; some reviews are referred to School-based reviewers or Committees.

Disclosure

NSF Project

NUCOI Office
No conflict identified

School Deans and/or
COI Oversight Committee
No Conflict

Conflict Managed

COI identified

Investigator
COI Management Plan developed

NUCOI Office

COI reported:
To sponsors as needed,
To the public upon written request.

Clinical Trial

NUCOI Office
Potential conflict identified

School Deans and/or
COI Oversight Committee
No Conflict

NIH Project

NUCOI Office
Potential conflict identified

School Deans and/or
COI Oversight Committee
COI Identified
Significant Financial Interests vs. Conflicts of Interest

A Significant Financial Interest (SFI) is any financial interest meeting the definition that is related to your university responsibilities and needs to be disclosed.

A Financial Conflict of Interest (FCOI or COI) is an SFI that could directly and significantly affect the design, conduct or reporting of specific research activity.

Equity interest in a nanomaterials company is a Significant Financial Interest if related to your University responsibilities. For example, if you:

1. Are a biomedical researcher performing preclinical studies in rodents evaluating the toxicity of nanoparticles delivering chemotherapy,

2. Ask your graduate student to do a “quick side project,” and evaluate a nanoparticle in the pipeline of your company, or

3. Do research on nanomaterials and are working on identifying a system that rapidly screens the properties of nanoparticles

The real or perceived Conflicts of Interest arise from:

1. Compromise of scientific objectivity in the conduct of research – If your company has similar particles or applications, it would be advantageous to find evidence of well-tolerated treatments

2. Use of students for personal outside company’s gain – Students are in an inherently vulnerable position; prior to engaging them in any company activities, consult your Dean’s office

3. Unfair access by a company to information or technology – The company could have unfair access to this system
What Happens if a COI is Identified?

If a COI 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 subjects
  - Reduced role in project
  - Independent data review and/or monitoring

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

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

**Investigator**
- Discloses SFIs
- Complies with NU policy
- Complies with COI management strategies (if applicable)

**Institution**
- Implements & enforces COI policy
- Evaluates SFIs and identifies FCOIs
- Manages FCOIs
- Reports FCOIs to study sponsors (as applicable)
- Complies with PHS and other sponsor policies

**Sponsor**
- Provides oversight

**NUCOI**
- COI Oversight Committee
- School COI Committee

Northwestern
What is Considered Noncompliance Relative to COI?

Noncompliance includes **failure to 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 by University Policy
- 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-funded research, noncompliance may result in the need for Northwestern to perform a federally-required retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research**
Questions? Concerns? Guidance?

Contact Northwestern’s Conflict of Interest Office (NUCOI)

Email: nucoi@northwestern.edu
Phone: (847) 467-4515
After reading this document, please return to eDisclosure to **Attest** to having reviewed this training...

AND THEN...

Click ‘Continue’ to complete your disclosure