Defining a Conflict of Interest

A situation where an individual’s external financial interests may bias or compromise – or *appear* to bias or compromise – an individual’s judgment, objectivity, or decision-making in research
How Do We Handle COIs?

• Disclosure of external interests and relationships
• Review of interests and research to identify COIs
• Elimination, reduction, or management of COIs
• Monitoring compliance with management strategies
Applicable Policies

Northwestern has three policies:

- Policy on Conflict of Interest and Conflict of Commitment
- Conflict of Interest in Research
- Institutional Conflict of Interest in Research
COI & COC at Northwestern

3 Disclosure Types:

• **Annual Faculty Disclosure** – completed once/year in February by faculty in eDisclosure

• **Annual Staff Disclosure** – completed once/year in February by staff in eDisclosure

• **Research Disclosure** – completed prior to engaging in research subject to Northwestern’s policy and on an ongoing basis

Researchers can meet research-related requirements simultaneously with annual disclosure requirements during the annual disclosure process each February. If no new interests/relationships arise during the year, annual disclosure alone is sufficient. If new interests/relationships arise outside of the annual disclosure process, researchers must update their disclosure within 30 days.
What Does a COI Look Like?

Not every disclosed interest/relationship is a COI

Examples of apparent or actual COIs related to research:

- Extensive consulting or other relationship with, or equity interest in, an entity sponsoring research
- Intellectual property rights for product being tested in research
- Use of students/support staff/university resources on external activities
- University dealings with entities with which a personal relationship exists
Why Are We Concerned About COI?

1. To protect the objectivity, credibility, and trustworthiness of our research, our research community (i.e. YOU), and our institution

2. To meet regulations that require the University to have policies and procedures for soliciting disclosure, review, and management of COIs
COI Regulatory Environment

- Project Terms & Conditions
- Institutional Policies
- Sponsor Requirements
- Federal Regulations: UG, PHS, NSF
Applicability of Northwestern’s COI in Research Policy:

• All **federally-sponsored** research
  – *PHS, NSF, DOD, DOE, DOJ, etc.*
• All **industry-sponsored** research
• All **human subjects research**, regardless of funding source
• Agencies that have adopted PHS COI regulations:
  – *AHA, PCORI, Susan G. Komen, etc.*
• Other sponsors with specific COI requirements

http://www.northwestern.edu/coi/policy/coi_by_sponsor.pdf
Important Terms

Investigator

Any individual acting as project director or principal investigator

AND

Any other person, regardless of position or title, who is independently responsible for the design, conduct, or reporting of research
## Important Terms

### Investigator

<table>
<thead>
<tr>
<th>Role on Project/Proposal Record</th>
<th>Investigator?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Key Personnel</td>
<td>YES - ALWAYS</td>
</tr>
<tr>
<td>Consultant</td>
<td>Individuals in these categories may or may not be Investigators subject to COI requirements. If there is any question as to whether an individual is an Investigator, the PI must confirm the assignment of project role.</td>
</tr>
<tr>
<td>Other Significant Contributor</td>
<td></td>
</tr>
<tr>
<td>Research Coordinator</td>
<td></td>
</tr>
<tr>
<td>Graduate Student / Postdoc</td>
<td></td>
</tr>
</tbody>
</table>

*Note: Department administrators or NUCOI may “deactivate” someone as an Investigator on a particular project in eDisclosure, with PI affirmation, if they are in this category and do not meet the definition of Investigator.*
Important Terms

Whether someone is an investigator is *not related* to their effort!

*For example:*  
The mentor of a graduate student or postdoc on a fellowship may have 0% effort because they are advisory, and may only meet with the trainee quarterly.

Do they significantly contribute to the design, conduct, or reporting of research? **YES.**
## Important Terms

### Investigator

<table>
<thead>
<tr>
<th>Role on IRB Study</th>
<th>Investigator?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principal Investigator</td>
<td>YES - ALWAYS</td>
</tr>
<tr>
<td>Co-Investigator</td>
<td>YES - ALWAYS</td>
</tr>
<tr>
<td>Study Team Member</td>
<td>NO</td>
</tr>
</tbody>
</table>
Important Terms

Institutional Responsibilities

• Any activity that is relevant to what you do at Northwestern. Common related activities include:
  – Editing, Scientific Advisory Board, Consulting, Training

• Things that are likely not related to an Investigator’s institutional responsibilities:
  – Retirement funds, Community Involvement (church groups, PTA service), etc.
Important Terms

Institutional responsibilities is a “grey area” –
Example: Your family owns a pizzeria. Disclose or not?

*Does it relate to your teaching, research, or clinical responsibilities?*

- “Getting a bigger piece of the pie: Capturing a larger share of a crowded market”

- Taste research on a secret formula that could be commercialized by your family’s restaurant

- Research on the health benefits of a gluten free crust that your restaurant uses
Important Terms

Significant Financial Interest (SFI)

An external financial interest for an Investigator and their Immediate Family Member, when aggregated for the 12 months preceding disclosure date, from a single entity, consisting of one or more of the specific interests in the definition.
Important Terms

**SFIs** include (see Appendix slides for full definition):

- **Any** equity in a non-publicly traded company
- Payment*, reimbursed travel*, equity in a publicly traded company†, or IP licensed outside of Northwestern valued at / exceeding $5,000♦

*Excluding federal, state, or local government agencies, US institutions of higher education, academic teaching hospitals, medical center or research institutes affiliated with an institution of higher education

†Excluding retirement accounts and mutual funds

♦FSM has a $0 disclosure threshold for compensation, intellectual property interests, and sponsored/reimbursed travel.
Important Terms

Financial Conflict of Interest (FCOI)

An SFI that could directly or significantly affect the design, conduct, or reporting of research
Where To Disclose

Log-in link:

https://coi.northwestern.edu
Northwestern’s Process

Investigator names are entered into InfoEd in Personnel Section
**If a person is on their first research project at Northwestern, email NUCOI to set them up in eDisclosure

Investigator names are fed into eDisclosure every 20 minutes

Compliance Checkpoint: Before submitting the grant, ALL investigators must have disclosed within the last year (365 days) and completed training within the last four years

InfoEd Proposal Status of the project is updated to “JIT,” “Prespend,” or any “Award” status – this triggers NUCOI review of the project

Compliance Checkpoint: Before opening the chartstring, ALL Investigators must have a status of “Review Complete”
Key Compliance Points (Initial)

Investigators:
- ✓ Disclose SFIs
- ✓ Complete COI training

NUCOI & School Deans
- ✓ FCOI determination made
- ✓ FCOI managed, as applicable
- ✓ FCOI reported, as applicable

OSR, ASRSP, & Departments

Proposal Submission

Funding Released
Tools for Meeting Compliance Points

- COI Compliance Page in eDisclosure

- FDP Clearinghouse: http://sites.nationalacademies.org/PGA/fdp/PGA_070596
Disclosure Review Process

- **Proposal can be submitted**: All investigators have disclosed
- **JIT Notification received**: Proposal status set to JIT; NUCOI begins review
- **NOA is received**: Proposal enters Award Workflow; OSR checks for COI determinations
- **Project can draw funds from sponsor**: Disclosures are reviewed, any conflicts are managed & reported

**Project Status**
- Disclosed
- Disclosed
- Disclosed

**Investigator Statuses**
- Disclosed
- Disclosed
- Disclosed

**Compliance Page Status**
- Review Complete
- Under Review
- Under Review

**NUCOI Reports to sponsor (if required)**

**Project**
- **JIT Notification received**: Proposal status set to JIT; NUCOI begins review
- **NOA is received**: Proposal enters Award Workflow; OSR checks for COI determinations
- **Project can draw funds from sponsor**: Disclosures are reviewed, any conflicts are managed & reported

**Projects are not reviewed until the status is set to JIT, Prespend, or an Award status**
A Note on Prespending

• Prior to drawing funds from the sponsor, a final COI determination must be on record for each Investigator named on the project, but *prespending* accounts can be opened prior to a final COI determination being made (i.e. when the COI review process is still underway)
  – Although prespending accounts can be opened before final COI determinations are reflected in *eDisclosure*, please note that each Investigator must have compliant training and disclosure dates on file prior to prespending accounts being opened
Key Compliance Points (Ongoing)

Investigators must:

- Disclose new SFIs within 30 days

- Disclose SFIs annually
  - All Staff & Faculty Investigators can do this during the Annual Disclosure process

- Complete COI training before engaging in research and every 4 years (or more frequently if required)
# Roles & Responsibilities

## Investigators
- Disclose financial interests related to their institutional responsibilities
- (PI) Identify all individuals who are Investigators on projects

## RAs / OSR
- Verify compliance of disclosure & training dates prior to proposal submission / project initiation
- Assist PIs in identifying all Investigators on a project

## NUCOI
- Review disclosed interests relative to research projects
- Work to manage, reduce or eliminate conflicts
- Report to sponsors, as needed
- Assist all other parties

## School Deans / Committees
- Review cases referred by NUCOI
- Assist in managing, reducing or eliminating conflicts for faculty and the institution
Resources

- Policy on Conflict of Interest and Conflict of Commitment:
  [Link](http://www.northwestern.edu/coi/policy/core_coi_policy.pdf)

- Policy on Conflict of Interest in Research:
  [Link](http://www.northwester.edu/coi/policy/research_policy.pdf)

- Northwestern’s Conflict of Interest Office:
  [Link](http://www.northwestern.edu/coi/index.html)

- FDP Clearinghouse:
  [Link](http://sites.nationalacademies.org/PGA/fdp/PGA_070596)
Questions?
Help/Assistance

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Significant Financial Interest

- Compensation and/or other payments for service (e.g., salary, consulting, advisory, and/or lecturing fees, paid authorship, gifts, and honoraria) exceeding $5,000*
- Equity interests (e.g., stock, stock options, or other ownership interests) in a publicly-traded entity for which the value exceeds $5,000
- Any equity interests (e.g., stock, stock options, or other ownership interests) in a non-publicly-traded entity
- Intellectual property rights and interests exceeding $5,000* (e.g., patents, copyrights), upon receipt of income related to such rights and interests
- Reimbursed or sponsored travel exceeding $5,000*

*FSM has a $0 value disclosure threshold.
Exclusions to SFI

• Compensation less than $5,000 (unless FSM)

• 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, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education, and compensation received from Northwestern funds
Exclusions to SFI

- Sponsored/reimbursed travel less than $5,000 (unless FSM)
- 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
- Intellectual property interests valued at less than $5,000 (unless FSM)
- Royalties received from Northwestern funds
- Unlicensed intellectual property that does not generate income
- Interests in publicly-traded entities valued at less than $5,000, as well as equity interests in any entity through personal retirement accounts and mutual funds