Conflict of Interest/Commitment

Conflict of Interest Office (NUCOI)

Kate Booth
Director, NUCOI
Overview

1. Defining COI, regulations & polices
2. Northwestern’s COI process – theory
3. Northwestern’s COI process – systems / workflow
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.
Why Are We Concerned About COI?

1. To protect the objectivity, credibility, and trustworthiness of our research, our research community, 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

- Federal Regulations (UG, PHS, NSF)
- Sponsor Requirements
- Project Terms and Conditions
- Institutional Policies
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

http://www.northwestern.edu/coi
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
How Does Northwestern Handle COI?

- 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
Disclosure Requirements: Who

Q: Who needs to disclose?
A: Investigators

- 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
### Who are Investigators?

#### Role on Project/Proposal

<table>
<thead>
<tr>
<th>Role on Project/Proposal</th>
<th>Is that person an Investigator?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Key Personnel</td>
<td><strong>YES - ALWAYS</strong></td>
</tr>
<tr>
<td>Consultant</td>
<td><strong>MAYBE</strong> – are they independently responsible for the design, conduct or reporting of the research?</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>

*If there is any question as to whether an individual is an Investigator, the PI must confirm the assignation of project role.*

#### Role on IRB Study

<table>
<thead>
<tr>
<th>Role on IRB Study</th>
<th>Is that person an Investigator?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principal Investigator</td>
<td><strong>YES - ALWAYS</strong></td>
</tr>
<tr>
<td>Co-Investigator</td>
<td><strong>YES - ALWAYS</strong></td>
</tr>
<tr>
<td>Study Team Member</td>
<td><strong>NO</strong></td>
</tr>
</tbody>
</table>
Who are Investigators?

Q: What if a person is **Key Personnel**, but has **0% effort**?
A: That person **is an Investigator** and needs to complete the COI requirements.

Effort is unrelated to the definition of Investigator

*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.**
Disclosure Requirements: What?

Q: What do Investigators need to disclose?

A: **Significant Financial Interests (SFIs)** related to their **Institutional Responsibilities**

- **SFI =**
  - Any equity / ownership / investment 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

- Common **related** activities include: Editing, Scientific Advisory Board, Consulting, Training
Disclosure Requirements: When?

Q: When do Investigators need to disclose?
A: Prior to proposing or initiating a project, and on an ongoing basis:

✓ when they have a new financial interest, and
✓ at least annually

Note! A grant cannot be submitted until all Investigators have completed a disclosure.
Disclosure Requirements: Where?

Log-in link:

https://coi.northwestern.edu
Disclosure Requirements

**Investigators** are required to disclose **outside financial interests / activities** that are **related to their Northwestern responsibilities** before proposing or participating in research, when they get a new interest, and **at least annually**
How Does Northwestern Handle COI?

- 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
Review: What Does a COI Look Like?

Not every disclosed interest/relationship is a COI
COIs are not necessarily bad things

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
How Does Northwestern Handle COI?

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
Manage: How do you manage a COI?

Transparency:
• Disclosure in publications, presentations & press releases
• Disclosure to research team members

Oversight / Firewalls / Separate Activities:
• Restrictions on use of resources (space, personnel, time, supplies) in company activities
• Requiring an SSJ for any purchases / vendor activity from company
How Does Northwestern Handle COI?

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
Where Does COI Fit in Workflows?

NUCOI works with OSR and the IRB to align processes and respond to shifting priorities.
Systems

Filters for projects subject to policy

Project details & personnel come in to eDisclosure

InfoEd

eIRB+

Database

Reports
Disclosure Review Process: Grants

- Project 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**

- Compliance Page Status
  - Review Complete

**Investigator Statuses**

- Disclosed
  - Disclosed
  - Disclosed

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

NUCOI Reports to sponsor (if required)
Compliance Checkpoints: Grants

**All investigators have:**
- Disclosed SFIs
- Completed training

**NUCOI & School Deans have:**
- Reviewed each Investigator and made a determination
- Managed any identified conflicts
- Reported any conflicts, as needed / applicable

Proposal can be submitted

Chartstrings can be issued
Disclosure Review Process: IRB Study

Proposal is submitted in eIRB+ and imported into eDisclosure

Study can be Approved by IRB
Disclosures are reviewed, any conflicts are managed & reported

Investigator Statuses

- Disclosed
- Disclosed
- Disclosed

At the time of import, NUCOI will reach out to any individuals who have not disclosed

COI tab status: Under Review

NUCOI / School communicates with investigator & study team to manage any identified conflicts

COI tab status: Conflict Managed

COI tab status: No Conflict

COI tab status: No Conflict

COI tab status: Under Review

COI tab status: Under Review
Compliance Checkpoints: IRB Study

All investigators have:
- Disclosed SFIs
- Completed training

NUCOI & School Deans have:
- Reviewed each Investigator and made a determination
- Managed any identified conflicts
- Reported any conflicts, as needed / applicable
- Communicated with Investigator/study team to request any needed changes to the study

Study can be Approved by IRB
Tools for Meeting Compliance Points

• COI Compliance Page in eDisclosure

- Go to: Discloser Page | COI Compliance Page

- Filter by: Project ID, SP001

<table>
<thead>
<tr>
<th>Project ID</th>
<th>IRB Protocol ID</th>
<th>Investigator</th>
<th>First Name</th>
<th>Last Name</th>
<th>Role</th>
<th>Training Date</th>
<th>Disclosure Date</th>
<th>Review Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>SP001</td>
<td>STU001</td>
<td>Joe Violet</td>
<td>Joseph</td>
<td>Violet</td>
<td>COI</td>
<td>2/7/2018</td>
<td>2/7/2018</td>
<td>Review Complete</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Susan Black</td>
<td>Susan</td>
<td>Black</td>
<td>COI</td>
<td>2/13/2018</td>
<td>2/13/2018</td>
<td>Review Complete</td>
</tr>
<tr>
<td></td>
<td></td>
<td>James Teal</td>
<td>James</td>
<td>Teal</td>
<td>COI</td>
<td>2/2/2018</td>
<td>2/2/2018</td>
<td>Review Complete</td>
</tr>
</tbody>
</table>

• COI tab in eIRB+

For information on COI reviews of IRB studies, please see the NU COI website.
Roles & Responsibilities

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

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

**RAs / OSR – RCs / IRB**
- Verify compliance of disclosure & training dates prior to proposal submission / project initiation / study approval
- Assist PIs in identifying all Investigators on a project

**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

Northwestern Conflict of Interest Office (NUCOI)
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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