Conflict of Interest/Commitment

Conflict of Interest Office (NUCOI)

Maria Daniele
Compliance Administrator
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<table>
<thead>
<tr>
<th>Conflicts</th>
<th>Financial, professional or other personal activities that affect, or <em>appear</em> to affect, a person’s judgment, commitment, or ability in carrying out University duties or responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>COI</td>
<td>A situation where an individual engages in outside activities, either paid or unpaid, that interferes with his or her primary obligation and commitment to the University</td>
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<tr>
<td>COI in Research</td>
<td>The risk that an individual’s external financial interests may bias or compromise – or <em>appear</em> to bias or compromise – an individual’s judgment, objectivity, or decision-making in research</td>
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COI & COC at Northwestern

3 Disclosure Types:

- **Annual Faculty Disclosure** – completed once/year in February by all faculty
  - FSM faculty of External Professional Relationships Survey
  - All other faculty complete their annual disclosure in FASIS

- **Annual Staff Disclosure** – completed once/year in February by all staff in FASIS

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

If a person is an Investigator, their annual survey will contain the research questions to update their research disclosure at least annually.
What Does a COI Look Like?

1. COIs are not necessarily bad
2. Not every external interest 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

Federal Regulations – in 2011, new regulations were released by the Public Health Service (PHS)

Sponsor Requirements

Institutional Policies

Project Terms & Conditions
Applicability of PHS regulations at NU

• NU’s COI policy applies PHS regulations to:
  – PHS agencies
  – Agencies that have adopted PHS COI regulations:
    – NSF
    – All industry-sponsored clinical trials
    – Other sponsors with specific COI requirements

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

**Investigator**

Any individual acting as project director or principal investigator

AND

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

### Investigator

<table>
<thead>
<tr>
<th>Role on Project</th>
<th>Investigator?</th>
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</thead>
<tbody>
<tr>
<td>Key Personnel</td>
<td>YES - ALWAYS</td>
</tr>
<tr>
<td>Consultant</td>
<td>Individuals in these categories <em>may</em> or <em>may not</em> be Investigators subject to COI requirements.</td>
</tr>
<tr>
<td>Other Significant Contributor</td>
<td>If there is any question as to whether an individual is an Investigator, the PI must confirm the assignation. Department administrators or NUCOI may “deactivate” someone as an Investigator on a particular project in FASIS, with PI affirmation.</td>
</tr>
<tr>
<td>Research Coordinator</td>
<td></td>
</tr>
<tr>
<td>Graduate Student / Postdoc</td>
<td></td>
</tr>
</tbody>
</table>
Important Terms

Investigator

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

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.
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.
What Needs to be Disclosed

New regulations broadened what needs to be disclosed

- Investigators must disclose significant financial interests (SFIs) that relate to any of their institutional responsibilities – *not just interests that may relate to the specific research activity*
Important Terms

Significant Financial Interest (SFI)

An external financial interest, when aggregated for the 12 months preceding disclosure from a single entity consisting of one or more of the specific interests in the definition
Important Terms

**Significant Financial Interest (SFI)**

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 NU valued at / exceeding $5,000♦

*Excluding federal, state, or local government agencies, 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 some categories.
Important Terms

Financial Conflict of Interest (FCOI)

An SFI that could directly or significantly affect the design, conduct, or reporting of research
How Do We Handle COIs?

- Disclosure
- Review
- Elimination, reduction, or management
Investigator names are entered into InfoEd in Personnel Section

Investigator names are fed (overnight) into FASIS COI system – New, non-faculty Investigators can now disclose

**Compliance Checkpoint:** Before submitting the grant, ALL investigators must have disclosed within the last year (365 days)

InfoEd Proposal Status of the project is updated to “JIT,” “Prespend,” or “Awarded” – this triggers NU COI review of the project

**Compliance Checkpoint:** Before opening the chartstring, ALL investigators must have “clear” COI statuses (either “No Conflict” or “Conflict Managed”)
A Note on Prespending

• Prior to drawing funds from the sponsor, a final COI determination must be on record, but *prespending* accounts can be opened before then, without a determination on file.
Where To Disclose

FASIS COI portal:
https://nupa.northwestern.edu/psp/pa91prod/EMPLOYEE/EMPL/h/?tab=PAPP_GUEST
Disclosure Review Process

- **Project Status**
  - Proposal can be submitted
  - All investigators have disclosed

- **JIT Notification**
  - Received: Proposal status set to JIT; NUCOI begins review

- **NOA is received**
  - Proposal status set to Awarded; OSR checks for COI determinations

- **Project can draw funds from sponsor**
  - Disclosures are reviewed, any conflicts are managed & reported

- **Investigator Statuses**
  - Disclosed

- **NUCOI Status & School Status**
  - No conflict

- **NUCOI Status**
  - Potential conflict

- **School Status**
  - No Conflict

- **School Status**
  - Conflict Managed

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

- Projects are not reviewed until the status is set to JIT, Prespend, or Awarded
Key Compliance Points (Initial)

Investigators:
- ✓ Disclose SFIs
- ✓ Complete COI training

OSR & Departments
- Proposal Submission
  - ✓ FCOI determination made
  - ✓ FCOI managed, as applicable
  - ✓ FCOI reported, as applicable

NUCOI & School Deans

OSR, ASRSP, & Departments

Funding Released
Key Compliance Points (Ongoing)

Investigators must:

- Disclose new SFIs within 30 days
- Disclose SFIs annually
  - All Staff & Faculty Investigators can now do this during the Annual Disclosure process!
- Complete COI training every 4 years (or more frequently if required)
Tools for Meeting Compliance Points

• FDP Clearinghouse: http://sites.nationalacademies.org/PGA/fdp/PGA_070596

• Monitor Compliance in FASIS: https://nupa.northwestern.edu/
Resources

Forms, Trainings & Tip Sheets!

http://www.northwestern.edu/coi/index.html
Resources

- Policy on Conflict of Interest and Conflict of Commitment:
  http://www.northwestern.edu/coi/policy/core_coi_policy.pdf

- Policy on Conflict of Interest in Research:
  http://www.northwester.edu/coi/policy/research_policy.pdf

- NU Conflict of Interest Office:
  http://www.northwestern.edu/coi/index.html

- FDP Clearinghouse:
  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 received less than $5,000,
- 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 NU funds
Exclusions to SFI

• Travel remuneration or sponsorship less than $5,000
• 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
• Royalties received from NU 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