Conflict of Interest (COI)
Policy & Process Overview

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Julia M. Campbell
Director, COI
Topics for Discussion

• Policy and Process Reminders & Updates
  – Applicability of NU’s COI policy and process
  – Travel disclosure threshold update
  – Disclosure timing clarity
  – Key process compliance points
  – Subrecipients and consultants
  – Contact Information
Applicability of NU’s Policy and Process

NU Policy applies PHS COI training and disclosure requirements to:

• PHS agencies;
• Sponsors abiding by PHS COI regulations;
• NSF;
• Sponsors with specific COI requirements; and
• Industry-sponsored clinical trials

New COI requirements apply to projects funded by these sponsors:

• New awards 8/24/12 or later
• New budget periods 8/24/12 or later
Who Must Disclose?

**Investigators**: individuals responsible for the design, conduct, or reporting of research.

*Key personnel? Consultants? Other significant contributors?* Individuals in these categories *may* or *may not* be Investigators subject to COI requirements.

If there is any question as to an individual being an Investigator or not 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.*
What Must be Disclosed?

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

*Faculty with primary appointments in FSM have different thresholds. Please read each question carefully.
## What Is Excluded from Disclosure?

<table>
<thead>
<tr>
<th>Nature of Interest</th>
<th>EXCLUDED FROM DISCLOSURE: DO NOT DISCLOSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compensation and/or other payments for service</td>
<td>• Compensation that aggregates to less than $5,000 (from one entity in the 12 months prior to disclosure date)*&lt;br&gt;• 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/or compensation received from or through NU funds</td>
</tr>
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<td>Equity interests in a publicly-traded entity</td>
<td>• Equity interests that aggregate to less than $5,000 (from one entity in the 12 months prior to disclosure date)*&lt;br&gt;• Interests in any entity through personal retirement accounts and mutual funds</td>
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<td>Intellectual property rights and interests upon receipt of income related to such rights and interests</td>
<td>• Interests that aggregate to less than $5,000 (from one entity in the 12 months prior to disclosure date)*&lt;br&gt;• Royalties received from NU funds, and unlicensed intellectual property that does not generate income</td>
</tr>
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<td>Sponsored or reimbursed travel</td>
<td>• Interests that aggregate to less than $5,000 (from one entity in the 12 months prior to disclosure date)&lt;br&gt;• 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.</td>
</tr>
</tbody>
</table>

*Faculty with primary appointments in FSM have different thresholds.
Please read each question carefully.*
Travel Disclosure Threshold Update

- Effective 1/1/13, the disclosure threshold for travel is $5,000 rather than zero. This means that Investigators need only disclosure sponsored and/or reimbursed travel (for themselves + spouse and dependent children) that exceeds $5,000 from a single entity in the 12 months prior to disclosure date.
- Investigators are welcome to continue to disclose all travel in the system if they feel it is easier to enter all travel as it occurs, rather than track on their own in order to disclose appropriately when travel from one entity exceeds the $5,000 disclosure threshold.
- This change results from an NIH Notice that allows institutions discretion in applying the $5,000 disclosure threshold to travel.
- Northwestern’s Policy on Conflict of Interest in Research has been updated to reflect this policy change effective 1/1/13.
Disclosure Timing Clarity

Disclosure is required:
• Prior to proposing or engaging in research subsequent to 8/24/12
• Within 30 days of a new SFI
• Annually (now consolidated with annual faculty COI requirements)

There is no need to prompt an investigator to disclose at JIT, NOA, or Progress Report Time UNLESS there is no disclosure on file in FASIS for the investigator.
Key Compliance Points

- Disclose SFIs
- Complete COI training

JIT/NOA/Contract Execution

- FCOI determination made
- FCOI managed, as applicable
- FCOI reported, as applicable

Proposal Submission

- OSR
- NUCOI/Schools

Award QA Check

- OSR

Funding Released

- ASRSP
Subrecipients and Consultants

As with many other federal regulations, Northwestern must flow down COI requirements to subrecipient institutions.

Proposals

• To ensure compliance with COI requirements, Northwestern must ensure the following information prior to proposal submission:
  – Department administrators/OSR should verify that a subrecipient institution is in the FDP COI Clearinghouse. If an institution is in the Clearinghouse, no other action is needed.
  – If an institution is NOT in the Clearinghouse, department administrators should work with OSR to ensure that language is included in the subrecipient's LOI that states that the institution has a COI policy that adheres to 42 CFR Part 50 Subpart F/45 CFR Part 94; or
  – Facilitate the subrecipient’s completion of the OSR Subrecipient Commitment Form.
Subrecipients and Consultants

IF – and only IF – a subrecipient institution elects to abide by Northwestern’s COI policy, department administrators should:

- Send the subrecipient institution Northwestern’s *Subrecipient/Consultant Investigator Conflict of Interest Disclosure and Certification Form*, and attach the PDF COI training document
- Each subrecipient Investigator on the proposed research project must complete the *Subrecipient/Consultant Investigator Conflict of Interest Disclosure and Certification Form*
- The subrecipient Investigator should submit the form directly to nucoi@northwestern.edu.
- NUCOI communicates with OSR so that subrecipient COI compliance is known prior to proposal submission.

Subrecipient forms available here: [http://www.northwestern.edu/coi/subrecipients/index.html](http://www.northwestern.edu/coi/subrecipients/index.html)
Subrecipients & Consultants

Awards

• Should a proposal be funded for which a subrecipient investigator and/or a consultant has agreed to adhere to Northwestern’s COI policy, a profile will be created for the individual as “POI” (person outside the institution) in InfoEd and FASIS at Just-in-Time (JIT) or as soon as notification of funding is received.

• This will allow the individual to complete a COI disclosure in the FASIS system.

• Any positive COI disclosures will be reviewed, COI determinations made, and any COIs related to the research managed, reduced, or eliminated prior to execution of the applicable subrecipient or consultant agreement and release of funding.
Questions/Help/Feedback?

Northwestern Conflict of Interest Office (NUCOI)

nucoi@northwestern.edu / 847.467.4515

Julia Campbell – Director
juliacampbell@northwestern.edu / 847.467.3938

Kate Cosgrove – Sr. Compliance Analyst
k-cosgrove@northwestern.edu / 847.491.4163

Maria Daniele – Compliance Coordinator
maria.daniele@northwestern.edu / 847.467.4515