Research Conflict of Interest (COI) Training Module

February 2017
Applicability

Completion of this training allows you to simultaneously meet the research-related COI training requirements for those engaged in research at Northwestern University, Lurie Children’s, or Northwestern Memorial Hospital.
Learning Objectives

At the end of this training module, you will:

• Understand the federal COI requirements that guide our institutional research COI policies 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, and how SFIs are reviewed

• Understand the term “Financial Conflict of Interest “ (FCOI)

• Understand how FCOIs are managed and when they may be reported to sponsors and/or 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.
What Must Institutions Do to Comply?

As a condition of federal funding, our institutions must establish procedures that provide a reasonable expectation that the design, conduct and reporting of research will be free from bias (or the perception thereof) resulting from Investigator Financial Conflicts of Interest (FCOIs {or COIs*}).

Federal regulations require that institutions:

1. Maintain a current, documented, and enforced COI policy
2. Educate Investigators as to 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 COI Requirements

• Investigators must disclose Significant Financial Interests (SFIs) related to their Institutional Responsibilities prior to engaging in research and on an ongoing basis

• Institutions determine whether an SFI could be a conflict of interest (COI) for each research project in which an Investigator is involved

• Institutions must eliminate, reduce, or manage COIs, and meet sponsor and other COI reporting requirements
Who Must Disclose & Where Does Disclosure Occur?

**Who must disclose?**

Investigators, defined as:

- Any person, regardless of title or position, who is independently responsible for the design, conduct or reporting of research
  - This includes Investigators at Northwestern, NMH, and Lurie Children’s
  - This may also include subrecipient institution and consultant Investigators, if applicable

**Where does disclosure occur?**

Disclosure occurs in the *eDisclosure* system:

https://coi.northwestern.edu
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 reasonably relates to their Institutional Responsibilities.

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

**Institutional Responsibilities**: activities that relate to your responsibilities on behalf of Lurie Children’s, NMHC, Northwestern, RIC, or the VA. Institutional Responsibilities include, but are not limited to: teaching, research, professional practice (including clinical practice), committee membership, and administrative activities and responsibilities for the institutions with which you are affiliated.
# What Must Be Disclosed?

<table>
<thead>
<tr>
<th>SFIs</th>
<th>Threshold/Description</th>
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<tbody>
<tr>
<td>Compensation and/or other payments for service</td>
<td>Any (from one entity in the 12 months prior to disclosure date)</td>
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<tr>
<td>Equity or other ownership interests in a publicly-traded entity</td>
<td>Exceeding $5,000 (from one entity in the 12 months prior to disclosure date)</td>
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<tr>
<td>Equity or other ownership interests in a non-publicly-traded entity</td>
<td>Any (i.e., ANY and ALL equity interests in non-publicly traded entities, even if worth $0 or for which the value is unknown)</td>
</tr>
<tr>
<td>Intellectual property rights and interests</td>
<td>Any (from one entity in the 12 months prior to disclosure date)</td>
</tr>
<tr>
<td>Sponsored or reimbursed travel</td>
<td>Any (from one entity in the 12 months prior to disclosure date)</td>
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## What Does **NOT** Need to be Disclosed?

<table>
<thead>
<tr>
<th>Nature of Interest</th>
<th>EXCLUDED FROM DISCLOSURE: DO <strong>NOT</strong> DISCLOSE</th>
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<tbody>
<tr>
<td><strong>General</strong></td>
<td>• Anything that does not meet the disclosure criteria or thresholds</td>
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<tr>
<td><strong>Compensation and/or other payments for service</strong></td>
<td>• 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 <a href="https://www.law.cornell.edu/uscode/text/20/part-1/chapter-1">20 U.S.C. 1001(a)</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 institutional funds at the institution at which you are employed.</td>
</tr>
<tr>
<td><strong>Equity interests</strong></td>
<td>• Interests in any entity through personal retirement accounts and mutual funds (403b, IRA, etc.)</td>
</tr>
<tr>
<td><strong>Intellectual property rights and interests</strong></td>
<td>• Royalties received from institutional funds at the institution at which you are employed</td>
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<tr>
<td><strong>Sponsored or reimbursed travel</strong></td>
<td>• Travel administered through institutional funds at the institution at which you are employed (including under research agreements/contracts awarded to the institution at which you are employed), 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>
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When do Investigators Need to Disclose?

• **Before engaging in research**
  - A disclosure must be on file in *eDisclosure* for each Investigator on a proposal before the proposal can be submitted to the sponsor by the institution, and/or before a protocol can be approved by the institution’s Institutional Review Board (IRB)

• **Within 30 days of a new SFI**
  - SFIs must be disclosed in *eDisclosure* within 30 days of acquisition, activity, or receipt of payment

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

Disclose new SFIs within 30 days of acquisition, activity, or receipt of payment

Annual Disclosure in February:
If you have no new SFIs through the year, the annual disclosure process will satisfy your annual requirement.

November 1: Received $6,000 consulting payment from BioOptical Experts, LLC
*Disclose this new consulting activity by 12/1*

March 5: Incorporate start-up company; Role = founder / owner; Value = $0
*Disclose this new equity interest by 4/5*

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

April 15: Received $3,500 payment for speaking at a conference, and $1,000 in reimbursed travel, from Takeda Pharmaceuticals
*Disclose this new speaking payment and reimbursed travel by 5/15*
Significant Financial Interests vs. Conflicts of Interest

- A Significant Financial Interest (SFI) is any financial interest meeting the definition that is related to your Institutional Responsibilities and needs to be disclosed
  - Not every SFI disclosed presents a COI

- 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
What Happens if a COI is Identified?

If a COI is identified, the institution 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 institution.

Certain COI information relative to PHS-funded research must be made available to the public upon request. The institution notifies Investigators prior to provision of such information.
What is Considered Noncompliance Relative to COI?

Noncompliance includes **failure to identify, review, or manage COIs** as required by federal regulations and institutional policy. The following are considered instances of Investigator noncompliance:

- Failure to disclose information as required by 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 your institution

Instances of non-compliance will be reviewed and disciplinary action taken, if needed, in accordance with applicable institutional policies and procedures.

**Relative to PHS-funded research, noncompliance may result in the need for the institution 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**
Complete Training

Please return to eDisclosure (by closing this window or clicking the “back” arrow on your browser) to attest to having reviewed this training by clicking the attestation checkbox on the training page.

Then, navigate through the disclosure in eDisclosure by clicking the “Continue” button to complete and submit your disclosure.