Conflict of Interest (COI): What’s All the Fuss About?

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Topics for Discussion

• How does Northwestern’s research COI process work?
• How does the COI Office, the FSM COI Committee, and the IRB Office work together?
• How can investigators and clinical research coordinators inform and influence an efficient and compliance COI process?
• How does the Sunshine Act impact Northwestern faculty researchers and our COI process?
• What initiatives are underway to streamline COI processes?
• Q&A
Impetus and Environment

“Biomedical and behavioral research and the resulting interactions among government, research Institutions, and the private sector have become increasingly complex.”

~ 42 CFR Part 50 Federal Register Notice Summary

“NIH's Plan for Public Disclosure Is Getting Help from Senator Grassley”
~ Project on Government Oversight, August 2011

“Baylor College of Medicine Faces NIH Sanctions Over Financial Conflicts”
~ Chronicle of Higher Education, January 2010

“29 Percent Of Cancer Studies Report Conflict Of Interest”
~ Science Daily, May 2009

"Top Psychiatrist Failed to Report Drug Income”

“Grassley Intensifies Probe Into NIH & Stanford”
~ Pharmalot, August 2008

“Drugmakers and College Labs - Too Cozy?”
~ Business Week, June 2008
Conflicts of Interest in our World

External relationships and financial interests have the potential to impact judgment and decision-making in academic, clinical care, research, and other activities.
Our Environment, Relationships, & Interactions

• Gifts from drug companies to physicians are ubiquitous
• Visits to physicians’ offices by drug and medical device company representatives and the provision of drug samples are widespread
• Many faculty members receive research support from industry, and industry funds most clinical trials in the U.S.
• Many faculty members and community physicians provide scientific, marketing, and other consulting services to companies; some serve on company boards of directors or on industry speakers bureaus
• Commercial sources provide about half of the total funding for accredited continuing medical education programs
Conflicts of Interest 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 in research.

- **External Interests**
  - Innovation
  - Entrepreneurship
  - $$$

- **Institutional Activities**
  - Objectivity
  - Data integrity
  - Safety & welfare

The relation - even potential or perceived relation - of external interests to institutional activities needs to be assessed.
Applicability

• NU’s research COI policy and process to any research sponsors with any COI requirements, which includes:
  – PHS-funded research
  – Research funded by agencies that have adopted PHS COI regulations
  – NSF-funded research
  – All industry-sponsored clinical trials
  – Other sponsored research as dictated by specific project terms and conditions
  • Check proposal solicitation/award/contract language!
Research COI Process Snapshot

• NUCOI and School Dean’s Offices review *each* investigator’s disclosure to assess significant financial interests (SFIs) compared to *each* body of research activity in order to identify any real or perceived COIs that could impact or bias the specific research activity.

• Not every SFI is an COI! A COI is an SFI that could directly and significantly impact the design, conduct, or reporting of research.

NU COI Disclosure

1. _______
2. _______
3. _______
4. _______
5. _______
6. _______

- Project # 1: No Conflict
- Project # 2: No Conflict
- Project # 3: Potential Conflict
- Project # 4: No Conflict
The following SFIs could present COI concerns relative to specific research activities:

- Compensation (for consulting, speaking activities, etc.) from an entity providing funding for the study and/or from an entity that manufacturers or markets a product or service being used in the study.
- Intellectual property rights relative to a product, service, or technique being tested in the study.
- Equity interests in an entity providing funding for the study and/or in an entity that manufacturers or markets a product or service being used in the study, and/or in an entity to which intellectual property rights are licensed.

A COI determination is made if an SFI relates to and could directly and significantly impact the research.
NUCOI and School Dean’s Offices (+ School-based COI Committees, if needed) review and make determinations regarding the reduction, elimination, or management of COIs where they do exist and report to research sponsors, as required.

Manage, reduce, or eliminate COI? We usually **manage** via a COI management plan.

COI determinations must be made prior to funding release. Some sponsors require **specific reporting** of COIs prior to funding release.
Key Compliance Points

**Investigators**
- Disclose SFIs
- Complete COI training

**Proposal Submission**
- FCOI determination made
- FCOI managed, as applicable
- FCOI reported, as applicable

**JIT/NOA/Contract Execution**
- OSR
- NUCOI/Schools

**Award QA Check**
- OSR

**Funding Released**
- ASRSP
Key Roles and Responsibilities

**NUCOI**

- Administer and oversee COI policies, processes, and systems
- Ensure University compliance with COI requirements
- Provide support to the University community relative to COI policies, processes, and systems
- Perform COI reviews
- Refer COI reviews to School Dean’s Offices and/or COI Committees as needed
- Monitor University compliance with COI requirements
- Conduct external institutional COI certifications and COI reporting as required
Key Roles and Responsibilities

Investigators

• Understand and comply with COI policies
• Complete initial and ongoing training and disclosure requirements
• Adhere to COI management plans (as applicable)
• Communicate with research team members relative to COI issues (as applicable)
Key Roles and Responsibilities

School Dean’s Offices/School COI Committees

- Conduct COI reviews
- Determine if an SFI is a FCOI for specific bodies of research activities
- Implement and oversee management plans
- Handle/respond to noncompliance as needed

Conflict of Interest Oversight Committee (COIOC)

- Oversee University COI program
- Review and resolve complex or cross-functional COI issues
  - Broad representation on COIOC
Key Roles and Responsibilities

Research Administrations/Coordinators

• Understand and comply with COI policies
• Support investigators relative to COI processes
• Be cognizant of, and facilitate compliance with, potential COI requirements at certain points in the research process
  - Proposal submission
  - IRB protocol submission
  - Award time/contract execution
  - Administering informed consent
  - IRB revisions
### Role Play

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<th><strong>DO</strong></th>
<th><strong>DON’T</strong></th>
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<td><strong>Do</strong> ask an investigator, if necessary and applicable, if they have relevant financial interests that need to be disclosed to the IRB and in the research subject informed consent document(s) for a particular study</td>
<td><strong>Do not</strong> ask an investigator to disclose the details of their personal financial interests to you or provide you with a copy of their COI disclosure</td>
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<td><strong>Do</strong> ask an investigator, if necessary and applicable, if there is a COI management plan relative to the study that includes information that you as a study team member need to be aware of (e.g., disclosure to subjects in informed consent document, restrictions around role in enrollment and consent processes, etc.)</td>
<td><strong>Do not</strong></td>
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Managing COIs in Clinical Research
Special Considerations for Clinical Research

• The nature of the research + parties and interests involved raise the stakes
  – Research involving human participants
  – Research involving drugs, devices, and biologics
  – Close funding and other financial ties among the healthcare industry, researchers, and research institutions
Special Considerations for Clinical Research

• Adequate protection of the rights and welfare of human research participants is paramount
  – What actions are necessary to minimize risks to participants?
    • Careful study design
      – Randomized, blinded studies
    • Disclosure
      – What information (nature and level of detail) should be provided to research participants regarding the source of funding, funding arrangements, financial interests of parties involved in the research, and any COI management strategies applied?
    • Lessened role of conflicted investigator in the research
      – More distant role relative to subject interaction, data analysis, etc.
    • Independent data review
      – Objective third-party review of study data (similar to DSMBs)
Disclosure to IRB and in Informed Consent Documents

There is a difference between “standard” template COI statement included in informed consent document and a specific *additional* COI statement that references an outside relationships/interests.

The following disclosure is made to give you an opportunity to decide if this relationship will affect your willingness to participate in this research study:

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<th>Standard</th>
<th>Specific (Examples)</th>
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<td>Your doctor, who is also the person responsible for this research study, is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before making your decision whether or not to be in the study.</td>
<td>Your study doctor receives compensation for consulting activities from Bristol-Myers Squibb, the manufacturer of the products being used in this study.</td>
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<td></td>
<td>Your study doctor receives compensation for speaking and advisory board activities from Boehringer Ingelheim Pharmaceuticals, the company providing funding for this study.</td>
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Disclosure to IRB and in Informed Consent Documents

IRB Office Template Language for COI Disclosure in Informed Consent:

http://irb.northwestern.edu/templates-forms/consent#Conflict of Interest
Sunshine Act: Key Facts

- *The Physicians Payment Sunshine Act* is part of the ACA
- The intent is to establish greater transparency regarding financial relationships among companies, physicians, and health care organizations
- While the University itself is not subject to the law, our faculty members who are physicians may be impacted; direct and indirect payments made to them will be reported by companies and posted in the public database
- Payments for research and education to Northwestern that ultimately compensates a portion of a physician faculty member’s salary may be reported by companies
- Faculty members are not required to actively do anything under the Law
  - However, faculty members may chose to review the information before it is made public and dispute inaccuracies (there is a review and dispute period prior to each annual public posting)
- Because information about faculty members’ outside interests and relationships is being made public, it is more critical than ever to ensure COI disclosures with the University are kept up-to-date and accurate
- Northwestern FAQs available here: http://www.northwestern.edu/coi/faq/Northwestern%20Sunshine%20Act%20FAQs.pdf
COI Changes in the New IRB World
Resources

• NUCCI website: http://www.northwestern.edu/coi/

• COI Management Plan Recommended Disclosure Language: http://www.northwestern.edu/coi/training/CMP_Recommended_Disclosure_Language.doc

• IRB Office Template Language for COI Disclosure in Informed Consent: http://irb.northwestern.edu/templates-forms/consent#Conflict of Interest

• FSM Regulatory Affairs Website (Conflict of Interest and Professional Integrity): http://www.feinberg.northwestern.edu/compliance/resources/coi-and-prof-integrity/index.html
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