Impacts of expanded COI Policy & new COI system on IRB-related submissions & processes

IRB Brown Bag
June 15, 2016

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Director, Conflict of Interest
Discussion Points

- Overview of key requirements
- Recent expansion of Northwestern’s COI in Research Policy and impact on IRB-related processes
- How various institutional offices and committees facilitate research-related COI reviews
- Factors considered and strategies utilized to manage COIs in the interests of protecting the rights and welfare of human research participants
- How COI information is shared with the IRB systematically now that the eDisclosure and eIRB+ interface is live
- Practical tips for CRCs and IRB administrators
What’s our objective?

Mitigating 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.

The relation - even potential or perceived relation - of external interests to research integrity and objectivity needs to be assessed.
Key Elements of COI Requirements

• Federal regulations require that institutions solicit investigator disclosures of outside interests, review compared to research activities to determine whether or not a COI exists, and eliminate, reduce, or manage any COIs.

• Institutions must designate institutional official(s) to meet these regulatory responsibilities.

• University policy assigns these responsibilities to NU COI and School Dean’s Offices (and COI Oversight Committee and/or School-based committees if/as needed).
  – VPR has designated the NU COI Director as Northwestern’s Authorized Institutional official for COI with federal regulatory agencies.
Policies & Disclosure Types

Policy on Conflict of Interest & Conflict of Commitment

- Annual Staff
- Annual Faculty

Policy on Conflict of Interest in Research

- Research
- Ongoing + Annual
  - Before proposal submission
  - Within 30 days of new interests
  - At least annually
COI in Research Policy Expansion

**Before February 15, 2016**
Research COI requirements applied to research proposed to/sponsored by any entities/agencies with any COI requirements
+ all industry sponsored clinical trials

**After February 15, 2016**
Research COI requirements apply to research proposed to/sponsored by any/all federal and industry sponsors
+ other entities/agencies with COI requirements
+ all research involving human research participants regardless of funding source
Impetus for Research Policy Expansion

• Uniform Guidance (UG) required all federal agencies to implement COI policies (ug!!!)
• Various disclosure points for researchers was causing confusion (university research COI system, annual FSM/affiliate COI system, COI question in eIRB)
• Collecting disclosure information in different places that was potentially inconsistent presents compliance risk
• Collecting COI information in eIRB presented potential accuracy and confidentiality concerns
• Opportunity of new COI system implementation to streamline and simplify requirements and processes
Research Policy Expansion: Communications

From: "Jay Walsh, Vice President for Research" <vp-research@northwestern.edu>
Reply-To: VP Research <VP-Research@northwestern.edu>
Date: Friday, February 12, 2016 at 11:45 AM
Subject: Revised Conflict of Interest in Research Policy-

NU Research community:

As you may have learned from recent communications, Northwestern is launching a new conflict of interest (COI) disclosure system on February 15th: eDisclosure. eDisclosure replaces the Faculty and Staff Information System (FASIS) for all research COI requirements. All staff and non-FSM faculty will also complete their annual disclosures in eDisclosure. Coinciding with this move to a new disclosure system, please note that effective February 15th, disclosure on a protocol-by-protocol basis in eIRB will no longer be required.

Northwestern’s COI in Research Policy has also been updated to provide clearer information and greater transparency with respect to research-related requirements and processes. The broadening of the policy applicability means that some researchers may be involved in the research-related COI process for the first time effective February 15th.

Key things to be aware of regarding the new system and updated policy:

- Research activity subject to the research-related requirements described in Northwestern’s COI in Research Policy will apply to all federal and industry-sponsored research, research sponsored by other organizations with specific COI requirements, and any research involving human research participants, regardless of funding source.
- All transactional disclosures will occur in eDisclosure beginning February 15th.
- Investigators are reminded that federal regulations and University policy require that new significant financial interests (SFIs) that arise throughout the year must be disclosed in eDisclosure within 30 days.
- Because the question regarding investigators’ related financial interests will no longer be asked in the eIRB protocol applications, it is critical that Investigators named on IRB protocols submitted to Northwestern’s IRB maintain the accuracy of their disclosures in eDisclosure throughout the year.

We believe the new system and its functionalities will benefit all involved in this process. The system is user-friendly and compatible to all computer types and browser platforms, and can be accessed securely online whether or not the user is on the Northwestern University network. Disclosures are easy to update and edit, and new response options that provide greater flexibility in answering questions have been incorporated based on feedback from Investigators. Management plan development by Schools, and Investigator approval of management plans, can occur easily within the system, and management plan information will be systematically provided to the IRB.

If you have questions, please contact Northwestern’s Conflict of Interest Office (NUCOI): nucoi@northwestern.edu 847-467-4515.

Thank you for your ongoing cooperation in this area.
Impacts of Research Policy Expansion

• Higher volume of individuals need to complete training and disclosures and go through research-related COI review process
  – More research proposals/projects covered under the policy
• Individuals subject to research COI process originate based on role in eIRB+ in addition to role in InfoEd
  – Investigators listed in Personnel section of InfoEd
  – PIs and co-Is listed on protocols in eIRB+
• No specific COI information collected in eIRB+; COI determinations interface from eDisclosure to eIRB+
  – Elimination of additional point of disclosure for researchers
• Consolidation and better overall management of COI compliance in terms of disclosure, review, and management
  – Single system and consistent review and management process
# Key Changes Resulting from eDisclosure – eIRB+ Interface

<table>
<thead>
<tr>
<th>Previous State</th>
<th>New State</th>
</tr>
</thead>
<tbody>
<tr>
<td>One individual represents in an eIRB protocol application whether or not anyone on the study team has financial interests related to the study</td>
<td>COI determination statuses display in eIRB application for PIs and co-Is on each study based on each individual’s full institutional COI disclosures that have been reviewed via process described in this session</td>
</tr>
<tr>
<td>Full COI management information is made available to IRB upon request (if IRB knows to request it)</td>
<td>Specific information regarding COI management for each investigator/study combination for which a COI determination has been made is uploaded in eIRB so that the IRB Office/IRB can assess whether or not they feel COI management strategies are adequate to protect human subject safety/welfare</td>
</tr>
</tbody>
</table>
eDisclosure – eIRB+ Interface

- Investigator Disclosure
- Research Project (if sponsored project)
- IRB Protocol
- This information facilities reviews COI reviews

NUCOI + Schools/eDisclosure

- COI Review
- COI Determination
  - No Conflict
  - Conflict Managed

This information feeds from eDisclosure to IRB+ for each investigator for each protocol

eIRB+

<table>
<thead>
<tr>
<th>Name</th>
<th>Role</th>
<th>COI Determination</th>
</tr>
</thead>
<tbody>
<tr>
<td>John Smith</td>
<td>PI</td>
<td>Conflict Managed</td>
</tr>
<tr>
<td>Carol King</td>
<td>Co-I</td>
<td>No Conflict</td>
</tr>
<tr>
<td>Henry Brown</td>
<td>Co-I</td>
<td>No Conflict</td>
</tr>
</tbody>
</table>

For any “Conflict Managed” determination, additional information is uploaded into eIRB+
### eDisclosure – eIRB+ Interface

**Example of information in eIRB for IRB/IRB Office access for COIs**

<table>
<thead>
<tr>
<th>DATA ELEMENT</th>
<th>SPECIFIC PROJECT/PROTOCOL COI INFORMATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol #</td>
<td>STU0012345</td>
</tr>
<tr>
<td>Title</td>
<td>Phase III study for Drug X in diabetes</td>
</tr>
<tr>
<td>Sponsor</td>
<td>Pfizer, Inc.</td>
</tr>
<tr>
<td>Name of Investigator with the COI</td>
<td>John Smith</td>
</tr>
<tr>
<td>Role on Study</td>
<td>PI</td>
</tr>
<tr>
<td>Name of the related entity</td>
<td>Pfizer, Inc.</td>
</tr>
<tr>
<td>Nature of COI</td>
<td>Consulting Remuneration</td>
</tr>
<tr>
<td>Value of the financial interest in last 12 months</td>
<td>Consulting Remuneration: $10K-19,999</td>
</tr>
<tr>
<td>Investigational Products (if applicable)</td>
<td>Drug X, FDA-approved being studied for an unlabeled indication</td>
</tr>
<tr>
<td>A description how the financial interest relates to the research and the basis for the Institution’s determination that the financial interest conflicts with such research</td>
<td>The purpose of this study is to assess the extent of Drug X’s efficacy in improving specific health conditions in diabetic patients compared to traditional standard of care for these conditions. Dr. Smith has a consulting relationship with the manufacturer of the investigational product in this study, which could present the perception of a conflict of interest that should be managed.</td>
</tr>
<tr>
<td>Considerations relative to FCOI determination and COI management</td>
<td>Multi-site study</td>
</tr>
<tr>
<td>Key elements of the Institution’s management plan</td>
<td>Disclosure of relationship with Pfizer to research team and collaborators</td>
</tr>
<tr>
<td></td>
<td>Disclosure of relationship with Pfizer in publications and presentations</td>
</tr>
<tr>
<td></td>
<td>Disclosure of relationship with Pfizer to IRB and in informed consent document(s)</td>
</tr>
</tbody>
</table>
What Happens To Disclosures

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.
What Happens To Disclosures

NUCOI and School Dean’s Offices (+ School-based COI Committees, if needed) review and make determinations regarding the reduction, elimination, or management of COIs if they do exist and perform reporting (if 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 reporting of COIs prior to funding release
COI Review Considerations

- The extent to which the conflicted individual could compromise the integrity of the data
- The extent to which the conflict could increase or add risk to the human subject
- The extent to which a COI, if identified, can be mitigated relative to potential data integrity and/or human participant welfare concerns
- Benefits to medicine, science, and public health that could accrue if the research is allowed to be conducted as planned
- The extent to which the reputations of the conflicted individual or institution could be damaged, even if the conflict is managed*

COI Management

COI management strategies:

• Disclosure
  – Transparency regarding the investigator’s related financial interests and relationships

• Independent data review
  – Independent data collection and/or analysis

• Lessened role of conflicted investigator in the research
  – Reduced role relative to subject interaction, enrollment, consent, data analysis, etc.
  – Not allowed to serve as PI
IRB Perspectives and Engagement in the COI Process

- There is constant communication among the IRB Office, NUCOI, and the FSM Dean’s Office/FSM COIC
- Faculty members who are also IRB members serve as representatives on the FSM COIC
- The Executive Director of the IRB Office and the Associate Vice President for Research (who oversees the IRB Office) serve as representatives on the FSM COIC
- The Associate Vice President for Research (who oversees the IRB Office) and the Chair of FSM’s COIC serve as representatives on the University’s COI Oversight Committee
Where IRB and COIC Goals Intersect

IRBs
- Respect for Persons
- Beneficence
- Justice

COICs
- Research Objectivity

Assurance that research subject safety and welfare are not negatively impacted by biased decision-making in research design, conduct, and reporting as a result of personal financial interests in research outcomes.
Key Take-Aways for CRCs/IRB Administrators

- Verify that all individuals named as PI and co-I on protocols submitted in eIRB+ have a disclosure on file in eDisclosure
  - Check “Compliance Page” in eDisclosure
- Need access? Contact NUCOI! nucoi@northwestern.edu
- If the person you are searching for does not appear in search results, contact NUCOI to ensure they have a profile set up appropriately, and we will facilitate ensuring that they disclose
Key Take-Aways for CRCs/IRB Administrators

- Encourage/remind researchers to update their disclosures in eDisclosure within 30 days of new SFIs -- annual disclosure is not sufficient if you are engaged in research and new SFIs arise throughout the year.

- If a PI or co-I references having a relationship with the study sponsor or manufacturer of a product under evaluation in a study, remind them to ensure their disclosure in eDisclosure is up-to-date to appropriately reflect the financial interest/relationship.

- Proactively include a disclosure statement in the informed consent document if/as applicable – it will save time later!

- Resources for disclosure language:
  - [https://irb.northwestern.edu/templates-forms/consent](https://irb.northwestern.edu/templates-forms/consent)
  - [http://www.northwestern.edu/coi/training/CMP_Recommended_Disclosure_Language.doc](http://www.northwestern.edu/coi/training/CMP_Recommended_Disclosure_Language.doc)
Key Take-Aways for CRCs/IRB Administrators

- Be patient – the policy expansion and eDisclosure and eIRB+ interface are new!
- The period after the annual disclosure process in February is the busiest time of year for NUCOI (we are starting to catch up now!)
- We are working to proactively identify PIs and co-Is on IRB protocols who do not have disclosures on file in eDisclosure to ask them to disclose, so as not to have hold-ups down the line with new awards/clinical trials/protocol approvals pending COI disclosure and reviews
- Contact me personally or NUCOI with questions/if you need help!
Questions/Discussion
Help/Assistance

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Key Links/Resources

Northwestern Conflict of Interest Office (NUCOI):
http://www.northwestern.edu/coi/

eDisclosure: https://coi.northwestern.edu

COI in Research Policy:
http://www.northwestern.edu/coi/policy/research_policy.pdf

One-Page Guide on Research COI Process for Investigators and Administrators:
http://www.northwestern.edu/coi/forms/One%20Pager%20Research%20Disclosure_vfinal.pdf

eDisclosure Compliance Page guidance:
http://www.northwestern.edu/coi/training/Monitor%20Compliance%20Page%20Guidance%20for%20RAAs.pdf