COI Updates

OSR Chicago Monthly Meeting Series

Julia Campbell
Director, Conflict of Interest Program

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Discussion Points

• New resource for faculty engaged in start-up companies
  – Key points for administrators to be aware of

• Refresh of key research COI process points relevant to administrators & coordinators
  – What research falls under Northwestern’s research COI policy and process?
  – What should I be aware of with regard to COI requirements and processes to facilitate award set-up, contract execution, and or IRB protocol approval?

• Q&A
New resource for faculty engaged in start-up companies
Topics Addressed in Guidelines

- Subcontracting to/from faculty start-up companies
- SBIRs/STTRs
- Use of Northwestern resources for faculty start-up company activities
- Involvement of students and post-docs in faculty start-up companies
- Purchasing equipment from faculty start-up companies
SBIRs/STTRs

Of specific note to research administrators, please note that Northwestern is not the prime applicant or awardee for SBIRs and STTRs; we may be engaged as a collaborator/subcontractor.

Northwestern administrators may not be involved in the proposal preparation or award administration of the company side of the SBIR/STTR; our involvement should relate only to the subrecipient (Northwestern) aspect of the project (e.g., providing LOI and statement of work; executing subagreement, etc.)
Refresh of key research COI process points relevant to administrators & coordinators
What research falls under Northwestern’s Research COI Policy & Process?

**Before February 15, 2015**
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
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
  – Named individuals 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 Research COI Process Points

**Investigators**
- ✓ Current disclosure on file
- ✓ Current COI training date

**OSR/IRB**
- ✓ Proposal Submission
- ✓ IRB Approval

@ JIT @ award @ full protocol record @ contract close to execution

**NUCOI/Dean’s Offices**
- ✓ COI review occurs
- ✓ COI determination made
- ✓ COI managed, as applicable
- ✓ COI reported, as applicable

Prior to

**OSR/IRB**
- ✓ Award Set-up
- ✓ Contract Execution
- ✓ IRB Approval
Tips for Administrators and Coordinators

- Verify that all individuals named as investigators in InfoEd and/or PI and co-I on protocols submitted in eIRB+ have a current 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
Tips for Administrators & Coordinators

❖ 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

❖ If/as applicable, 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
  ❖ http://www.northwestern.edu/coi/training/CMP_Recommended_Disclosure_Language.doc
Key Take-Aways for Administrators & Coordinators

- NUCOI’s website hosts an abundance of tip sheets, guidance, and training materials that may help you navigate through the research COI process *(including a page just for administrators, a page relative to the subrecipient process, and more!)*

- If a faculty member you serve has a start-up company engaged in Northwestern research, read (and share!) the new guidelines for navigating the inherent complexities in such intersections of activities

- Contact NUCOI with questions or for assistance!
Help/Assistance

Northwestern Conflict of Interest Office (NUCOI)

nucoi@northwestern.edu / 847.467.4515

Julia Campbell – Director
juliacampbell@northwestern.edu / 847.467.3938

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

Garth Huskey – Compliance Analyst
garth.huskey@northwestern.edu / 847.467.6050

Paula Foster – Program Assistant 4
p-foster@northwestern.edu / 847.467.4515

PLEASE use main email address for requests and questions: this allows us to triage to best serve you
Key Links/Resources

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

eDisclosure: [https://coi.northwestern.edu](https://coi.northwestern.edu)


Questions/Discussion