

COI Updates

OSR Chicago Monthly Meeting Series

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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



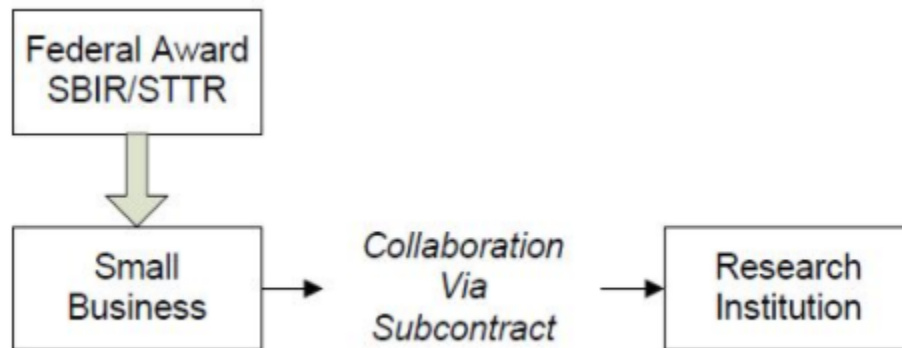
Topics Addressed in Guidelines

- 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

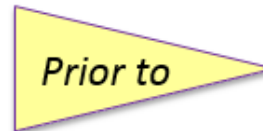
Impacts of Research Policy Expansion

- 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



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


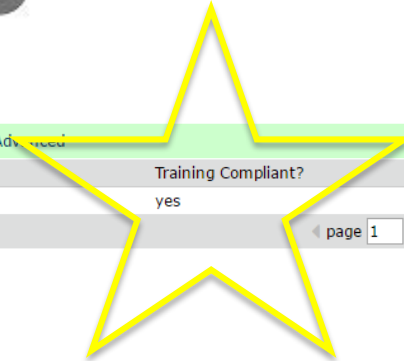
eDisclosure

Search by Project **Search by Person**

Filter by Last Name ▼ chisholm Go Clear Advanced

Last Name	First Name	COI Training Date	Training Compliant?	Last Submission Date	Disclosure Compliant?
Chisholm	Rex	9/15/2012	yes	4/16/2016	yes

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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)

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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/>

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

Guidelines for Navigating COI Issues when Faculty Start-Up Companies Engage in University Research:

<http://www.northwestern.edu/coi/guidelines-for-navigating-coi-issues-when-faculty-start-up-companies-engage-in-university-research.html>

eDisclosure Compliance Page guidance:

<http://www.northwestern.edu/coi/training/Monitor%20Compliance%20Page%20Guidance%20for%20RAs.pdf>

Questions/Discussion

