

Conflict of Interest Program

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October 16, 2019

Northwestern

Overview:

Conflict of Interest

- What are conflicts; why do we have an office?
- What does our office do?
- When do we need help?

Foreign Interference

- Update on information from federal sponsors
- What do we expect from research administrators? From faculty?

Conflict of Interest

What are conflicts?

A conflict of interest is a **situation** where financial, professional or other outside personal activities or interests affect, or appear to affect, a person's judgment in carrying out their University duties or responsibilities.

- Does not indicate wrongdoing
- Is not research misconduct
- Does not guarantee decisions will be biased
- Does create the opportunity for bias to be introduced
- May raise questions about motives
- Should be managed and handled appropriately

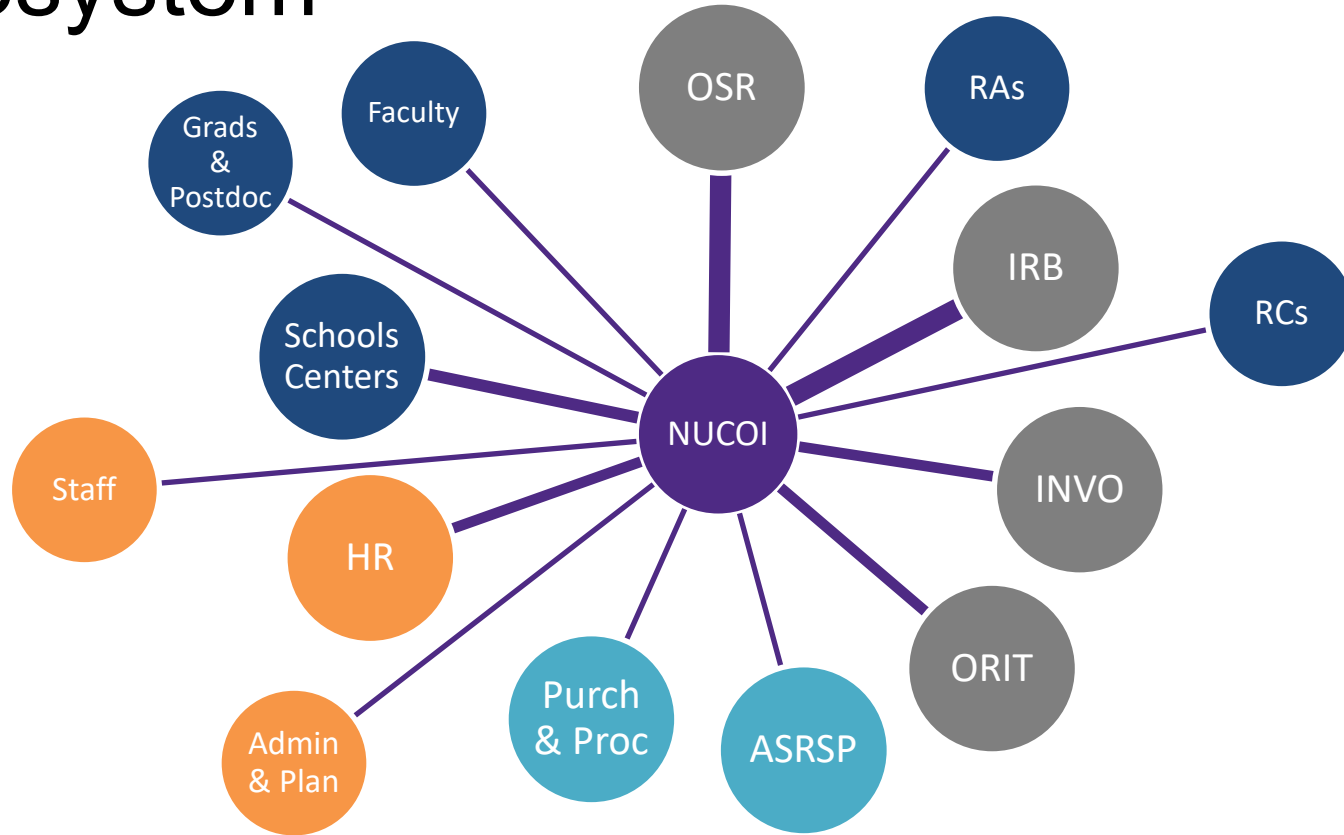
What do conflicts look like at a university?

- Senior administrator instructing a department to use a vendor that s/he has a financial relationship with
- Sale of a university asset to a company that the university and/or decision-maker has a financial interest in without opening the sale up for bid

What do conflicts look like in research?

- Performing research sponsored by an entity where there is an external relationship
- Subcontracting to a company where there is a financial relationship
- Purchasing equipment or services from a company where there is a financial relationship
- Having people in the lab that are employed both by the university and a company – all reporting to the same “boss” at both entities
- Sending data to the PI’s start-up company prior to publication
- Validating the effectiveness of a widget that has recently been licensed
- Prioritizing company use of a piece of equipment over a graduate student’s thesis project

Ecosystem



Northwestern's COI Process



Disclosure of outside professional activities and interests



Review of interests and responsibilities / research to identify COIs

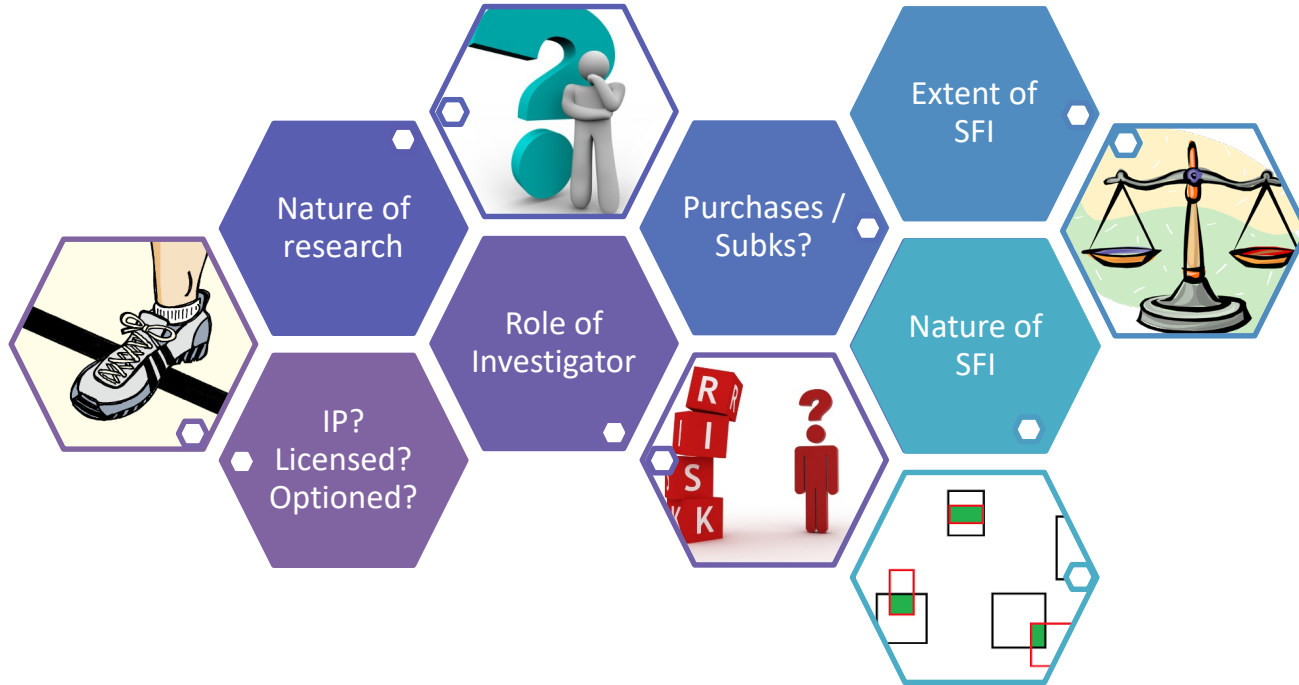


Elimination, reduction, or management of COIs



Monitoring compliance with management strategies

Factors considered in COI Reviews



What do we look at in a review?

- Project
 - Aims
 - Budget (capital equipment, subk's, F&A waivers, etc.)
- Company
 - “About Me” – what is the goal of the company?
- Investigator
 - Role on project
 - Role in company
 - Northwestern appointment type
 - Licensed IP?

What do we look at in a review?

- Is there overlap between the goals of the project and the goals of the company such that:
 - The company would unfairly benefit from the work? (e.g., improving IP that is licensed / optioned to the company)
 - Decisions about the design, conduct, or reporting of the research could be biased – or ***appear*** to be biased – by the outside company?

Northwestern's COI Process



Disclosure of outside professional activities and interests



Review of interests and research to identify COIs



Elimination, reduction, or management of COIs



Monitoring compliance with management strategies

Management Plans

Transparency:

- Disclosure in publications, presentations & press releases
- Disclosure to research team members

Oversight / Firewalls:

- Restrictions on use of resources (space, personnel, time, supplies) in company activities
- Engaging students requires an agreement
- Restrictions on negotiating contract terms between the company and Northwestern
- Requiring an SSJ for any purchases / vendor activity from company
- Changing reporting lines if there is an outside relationship
- Reminder of the Patent & Invention policy

What things are hard stops*?

Things that violate (or look like a violation of) regulations

- Serving as PI on both sides of a subcontract – subcontracting to yourself
- Large purchases from a start-up company using federal funds

Things that jeopardize the university's status and accreditation

- Using ACUC or IRB services without an appropriate research agreement in place
- Using Northwestern address / phone numbers as a “place of business” for the company (unless...)

Things that are high risk

- Clinical research with products developed at Northwestern

**Note: Northwestern is supportive of faculty entrepreneurial efforts – compelling circumstances (and documentation!) can overcome these*

Resources

*AKA: There's a **right way** to do things...*

Start-up company guidelines

- Subcontracting to/from start-ups
- SBIRs/STTRs
- Use of Northwestern resources (e.g., equipment or space)
- Involvement of students & postdocs
- Purchasing

When does NUCOI need help?

- Encourage transparency and disclose outside professional activities
- Reach out when something comes up:
 - Requests to spend discretionary funds on a start-up company
 - Proposed subcontract to a start-up company
 - Purchasing or vendor-add request

Foreign Interference

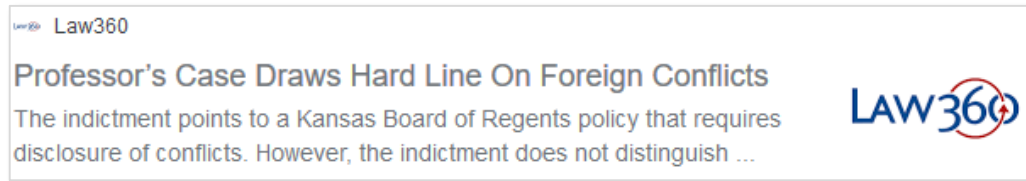
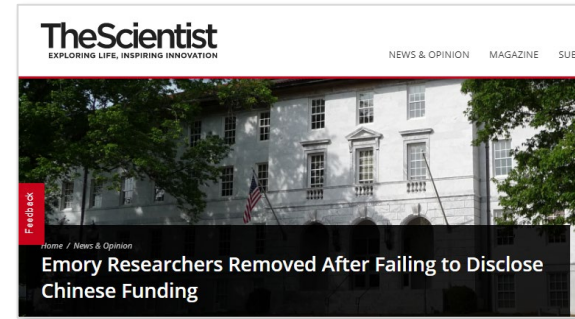
Headlines

- Duke: Graduate student allegedly passed data and IP to collaborators in China without going through proper channels - including Air Force-sponsored research
- Argonne National Lab: Per DOE memo, participation in talent recruitment programs banned (March)
- MD Anderson: fired three scientists (April); flash drives and active USB ports now banned (May)



Headlines (cont'd)

- Emory: Two scientists fired for not disclosing funds received from Chinese sources & the extent of involvement with a research institution in China (May)
- Kansas: Professor indicted for failing to disclose employment contract with a Chinese university (September)



Information from federal gov't

- Investigators funded by federal dollars are expected to disclose their relationships – including those with foreign governments or universities – to their institutions, and sponsors, as required.
- ***Focus: You cannot receive funding for the same project twice – you cannot double-dip.***
- Failure to appropriately disclose these relationships can be construed as fraud.

Sponsor	Support Document	Titled or Honorary Appointment @ other institution	Visitor with their own funding	Access to laboratory space at other institution	Significant collaboration even if no funds spent	Materials transferred in-kind	Consulting / Other time commitments
All	Biosketch – Proposal	Yes		Yes Role or appointment			
NIH	Other Support – JIT & RPPR		Yes Term of service and institution	Yes Institution and term	Yes Collaborator name and institution.	Yes, <u>if</u> used in the project	
	Foreign Component - RPPR			Yes, <u>if</u> foreign & work will occur there	Yes, <u>if</u> foreign collaborator & work will occur there	Yes, <u>if</u> used and from a foreign institution	
NSF	Current & Pending (effective date TBD)	We will update once the PAPPG for 2020 is finalized and released; however we would advise transparency similar to the NIH’s guidance in the meantime.					
Other	Other support			Yes Institution and term			

Examples for Other Support Disclosures

Agreement Type: MTA for antibody x,y,z

Collaborator: John Doe, Smithsonian Institution

Dr. XXX has significant collaborations with the following individuals who may be co-authors on publications resulting from this award:

Collaborator Name:

Institution:

Funding source (if applicable): [Agency/Sponsor] (Award #)

Dr. XXX has a visiting scholar funded by [Institution name] from (start date – end date)

Dr. XXX has access to laboratory space, equipment, and personnel at [Institution name] via their [honorary / visiting appointment], which is funded by [Institution / agency / etc.].

Resources

- Northwestern Guidance
 - [Op-Ed Co-Authored by President Morton Schapiro](#)
 - [Office of Research Guidance Regarding Foreign Influence and Involvement in University Research \(February 7, 2019\)](#)
 - [FAQs on Foreign Influence \(August 2019\)](#)
 - [OSR Tools & Forms](#)
 - [COI: What to Disclose?](#)
 - [Export Controls Compliance](#)
- Department of Defense (DoD)
 - [H.R.5515: John S. McCain National Defense Authorization Act for FY 2019](#)
 - Letter re: foreign interference and expectation to include appointments in other support documentation (October 2019)
- Department of Energy (DoE)
 - [Memo on Department of Energy Policy on Foreign Government Talent Recruitment Programs](#) (Jan 31, 2019)
- National Science Foundation (NSF)
 - [Memo from Senate Finance Committee to NSF \(April 15, 2019\)](#)
- NIH
 - [Presentation “Foreign Influences on Research Integrity” \(December 13, 2018\)](#)
 - [Foreign Influence Letter from NIH Director Francis Collins \(August 20, 2018\)](#)
 - [NOT-19-114: Reminders of NIH Policies on Other Support and on Policies related to Financial Conflicts of Interest and Foreign Components \(July 2019\)](#)