Conflict of Interest Program

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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
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

- Nature of research
- Role of Investigator
- IP? Licensed? Optioned?
- Purchases / Subks?
- Extent of SFI
- Nature of SFI

Northwestern
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.
<table>
<thead>
<tr>
<th>Sponsor</th>
<th>Support Document</th>
<th>Titled or Honorary Appointment @ other institution</th>
<th>Visitor with their own funding</th>
<th>Access to laboratory space at other institution</th>
<th>Significant collaboration even if no funds spent</th>
<th>Materials transferred in-kind</th>
<th>Consulting / Other time commitments</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>Biosketch – Proposal</td>
<td>Yes</td>
<td>Yes Role or appointment</td>
<td></td>
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</tr>
<tr>
<td>NIH</td>
<td>Other Support – JIT &amp; RPPR</td>
<td>Yes Term of service and institution</td>
<td>Yes Institution and term</td>
<td>Yes Collaborator name and institution.</td>
<td>Yes, if used in the project</td>
<td>Yes, if used and from a foreign institution</td>
<td></td>
</tr>
<tr>
<td>NSF</td>
<td>Current &amp; Pending (effective date TBD)</td>
<td>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.</td>
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<tr>
<td>Other</td>
<td>Other support</td>
<td></td>
<td>Yes Institution and term</td>
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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-Author 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)
  - QSR Tools & Forms
  - COI: What to Disclose?
  - Export Controls Compliance

- Department of Defense (DoD)
  - 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)