WHAT DO I NEED TO KNOW ABOUT CONFLICT OF INTEREST?

Angie Solomon
March 11, 2015

Welcome

Overview

What is COI?

What are the ground rules?

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What is the role of the Research Integrity Office?

How can you help?

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What is COI?

A conflict of interest exists when a primary interest or responsibility is (unduly) affected by a secondary interest or responsibility.

PHS FCOI definition

Financial conflict of interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

Types of Conflict

- Personal vs. Institutional
- Financial vs. Other
  - Prestige
  - Promotion
  - Reputation
  - Belief in idea
  - Purchasing
  - Nepotism
  - Clinical
  - Etc.
Why Do We Care about COI?

- Protection of human subjects
- Protection of our faculty, staff and institution
- Federal regulations and requirements
- Maintain the public’s trust
- Complete transparency

What are the ground rules?

- Most COI Policies are based on the PHS rules issued in August 2011 that went into effect August 24, 2012.
  

- Duke Policies
  
  [http://medschool.duke.edu/research/research-integrity-office/coi-related-policies](http://medschool.duke.edu/research/research-integrity-office/coi-related-policies)

PHS/NIH Requirements for COI

NIH requires grantees and investigators to comply with requirements of 42 CFR Part 50, Subpart F for research where PHS funding is sought.

- Organizations must:
  
  - Have a written and enforced administrative process to identify and manage, reduce, or eliminate conflicting financial interests with respect to research projects for which NIH funding is sought.
  
  - Before spending any NIH funds awarded under a new award, inform the Grants Management Officer (GMO) of the existence of any conflicting financial interests.
PHS/NIH Requirements for COI...cont

- Sponsored travel must be reported.
  - https://radapps.duke.edu/phs_travel
- Individuals funded by PHS/NIH must have training.
  - http://www.safety.duke.edu/OnlineTraining/compliancecourses.asp
- FCOI info must be made publicly available when requested.
- Reporting of conflicts to eRA Commons is more detailed and is now an annual requirement.

Duke rules match the PHS rules with two notable exceptions:

- We do have an institutional COI policy that may require management of human subjects research on ideas developed at Duke, even if the investigators have no personal COI.
- We consider royalties paid through the institution to be possible source of COI.

Agencies Using the PHS FCOI Regulations

Public Health Service (PHS) Agencies:
- Office of Global Affairs (OG)
- Office of the Assistant Secretary for Health (OASH)
- Office of the Assistant Secretary for Preparedness and Response (ASPR)
- Agency for Health Care Research & Quality (AHRQ)
- Agency for Toxic Substances and Disease Registry (ATSDR)
- Centers for Disease Control and Prevention (CDC)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- Indian Health Service (IHS)
- National Institutes of Health (NIH)
- Substance Abuse and Mental Health Services Administration (SAMHSA)

Non-PHS Agencies:
- Alliance for Lupus Research (ALK)
- American Asthma Foundation
- American Cancer Society (ACS)
- American Heart Association (AHA)
- American Lung Association (ALA)
- Arthritis Foundation (AF)
- CurePSP
- Juvenile Diabetes Research Foundation (JDRF)
- Lupus Foundation of America (LFA)
- Patient-Centered Outcomes Research Institute (PCORI)
- Susan G. Komen for the Cure
Research COI vs. Administrative COI

Who submits a form:

<table>
<thead>
<tr>
<th>Research</th>
<th>Administrative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regular Rank Faculty</td>
<td>Certain Administrators – e.g. Business Managers, all staff in certain areas such as Compliance, and staff identified by their department as having duties related to potential coi issues</td>
</tr>
<tr>
<td>Individuals involved in the design, conduct, or reporting of research</td>
<td></td>
</tr>
<tr>
<td>Individuals involved in clinical care (DUAP faculty, Hospitalists, ER Physicians)</td>
<td>Individuals involved in clinical care (PA, NP, Pharmacists)</td>
</tr>
<tr>
<td>Covered Officials (high-level leadership)</td>
<td>Covered Officials (high-level leadership)</td>
</tr>
<tr>
<td>Subcontractors and Subrecipients that do not fall under their own PHS-compliant policy</td>
<td></td>
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Form Due Dates

Administrative Call
- Usually second week in January.
- Forms due February 15
- Within 30 days of a change.

Research Call
- Usually second week in March.
- Forms due April 30
- Within 30 days of a change.

Whether Administrative or Research:

In terms of COI, generally you should maintain separation between your Duke responsibilities and your work with external companies.

However, you should disclose the outside relationship when applicable. Examples of when to disclose:

- When in discussions of competitors of the entity
- Any time your objectivity could be called into question by not disclosing the information
What is the role of the Research Integrity Office?

Research reviews:

- Provide guidance to researchers related to COI.
- Evaluate and manage sources of potential bias.
- Protect human subjects (by limiting the roles of conflicted investigators).
- Evaluate whether the research might lead to personal inurement (use of institutional resources for personal gain).
- Evaluate whether research is consistent with our non-profit mission.
- Includes reporting to outside agencies regarding COI, when appropriate.

Research COI

What is a Significant Financial Interest - SFI

- $5,000 or > /year in payment
- $5,000 or > in equity value (publically traded)
- Any privately held equity or options
- Royalty rules
  - Apply on a case-by-case basis to non-institutional payments ($5,000 or >)
  - Allowed to exempt payments through the institution
  - Duke treats royalties as income regardless of whether it comes through the institution

Administrative Reviews

- Provide guidance to administrators related to COI.
- Evaluate and manage sources of potential bias.
- Evaluate whether the outside relationship might lead to personal inurement.
**Other responsibilities:**

- Review Open Payments Database – Physicians Sunshine Act (compare against our forms)
- Review grants as awarded for potential COI
- Review positive DPAP's
- Review/manage as needed subcontractors and subrecipients
- Ensure 100% compliance for form completion of researchers (with a lot of help from departments)
- Provide periodic reports to:
  - Senior leadership
  - Department Chairs
  - DECO
  - DUHS Compliance Office
  - Others upon request

**How can you help?**

Here are just a few ways:

- Encourage timely completion of COI forms.
- Encourage updates to COI forms when relationships change.
- Talk to the PI before submitting a DPAF to be sure it is correct.
- Respond to and encourage prompt replies to RIO emails and requests.
- Encourage investigators to contact RIO before entering into consulting agreements with companies they receive research support from or before taking on research projects for companies they consult for.
- Contact RIO when there are COI questions.

**Summary**

What is the take away?

COI is NOT a black and white issue...we live in the world of gray. Every situation needs to be reviewed on its own. There are some guidelines but because there are so many variables if you are not sure if a situation is allowable or not, check with RIO.

http://medschool.duke.edu/research/research-integrity-office
### Who do I contact?

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
<th>Phone</th>
<th>Email</th>
</tr>
</thead>
<tbody>
<tr>
<td>Susan Aldridge</td>
<td>Staff Specialist</td>
<td>684-3121</td>
<td><a href="mailto:susan.aldridge@dm.duke.edu">susan.aldridge@dm.duke.edu</a></td>
</tr>
<tr>
<td>Tammy Gentry</td>
<td>Administrative Coordinator</td>
<td>613-2163</td>
<td><a href="mailto:tamera.gentry@dm.duke.edu">tamera.gentry@dm.duke.edu</a></td>
</tr>
<tr>
<td>Susan S. Brooks</td>
<td>Administrative Coordinator</td>
<td>684-6757</td>
<td><a href="mailto:susan.s.brooks@dm.duke.edu">susan.s.brooks@dm.duke.edu</a></td>
</tr>
<tr>
<td>Angie Solomon</td>
<td>Administrative Manager</td>
<td>684-1822</td>
<td><a href="mailto:angela.solomon@dm.duke.edu">angela.solomon@dm.duke.edu</a></td>
</tr>
<tr>
<td>Ross McKinney, MD</td>
<td>Chair, COI Committee</td>
<td>668-9000</td>
<td><a href="mailto:ross.mckinney@dm.duke.edu">ross.mckinney@dm.duke.edu</a></td>
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### Questions?

- What are the contact details for Susan Aldridge?
- How can I reach Tammy Gentry?
- Who is Susan S. Brooks and what role does she hold?
- What is Angie Solomon's title and how can I contact her?
- Who is Ross McKinney, MD, and what is his role?