Research Conflicts of Interest

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Jodi Edelstein
Manager, Conflicts of Interest
Office of Research Compliance
Our Team

Office of Research Compliance (the ORC)

Ara Tahmassian
Associate VP
Research Compliance
BU/ BMC

Kate Mellouk
Executive Director
Research Integrity
BU/ BMC

Jodi Edelstein
Compliance Manager
Conflicts of Interest
BU/ BMC

Leilani Hernandez
Compliance Coordinator
Conflicts of Interest

Charles River Campus
Faculty Committee on Research Conflicts of Interest

BU MC
Faculty Committee on Research Conflicts of Interest
The Core of What We Do

Protect the Objectivity of Research by Reviewing and Managing Conflicts of Interest in Research

Conflict of Interest - when a private interest could unduly affect a professional decision

e.g., You get royalties for your invention, and are about to conduct research to test how effective it is.

Private financial interest in royalties might cause one to make personally favorable decisions with regard to the design, conduct or reporting of research, even unconsciously!
Of the many, many causes of **bias** (i.e., conflicts) in research, we look for:

- Payments for professional services
- Patents, copyrights (IP) and related royalties
- Equity holdings (stock)
- Honorarium
- Gifts

...but *only* where they could **directly** and **significantly** affect the design, conduct, or reporting of Research at BU or BMC.
What We Do

1) Policy
   • Write, refine and implement it
   • Keep up-to-date on latest developments in the field

2) Handle FCOI (financial conflict of interest) Cases
   • Gather and review financial disclosures
   • Decide on conflict of interest “management plans”
   • Monitor compliance with management plans
   • Reporting FCOIs and plans to sponsors

3) Educate and Advise
   • Faculty and staff, as requested
   • Via presentations in the community
COI policies at Boston University and Boston Medical Center

**Investigator Conflicts of Interest**
- Private interests held by research project investigators, their spouse and dependent kids

**Institutional Conflicts of Interest**
- Boston University’s interests, as an institution
- Private interests and roles of key individuals

COIs exist → People care → Federal Gov’t cares → Institutions care
Institutional Conflicts of Interest Policy

- “Significant” financial interests (which *might* constitute an FCOI):
  - Boston University’s interests: equity, royalties and gifts to BU
  - Key individuals: equity, IP interests, non-BU/BMC compensation, or outside positions relating to research

- “Key individuals” = a person who has influence over what research is conducted and also, provides research oversight and review. Provosts, VPs, Deans, Chairpersons, etc.

- No reporting to the federal government required.
- Possible “pause” on research or management plan where FCOI is found.
Investigator Conflicts of Interest Policy

• “Investigator” means: Someone responsible for design, conduct or reporting of research

• Investigators Disclose:
  a) Salary or other payments for services (consulting fees, sponsored travel, honoraria)
  b) Stocks, stock options (aka equity)
  c) Royalties in connection with intellectual property rights (patents, copyrights)

    ✓ Must be related to institutional responsibilities
    ✓ Includes holdings of spouse and dependent children

• “Research” included: a systematic investigation, study or experiment... designed to develop or contribute to generalizable knowledge ...designed, conducted or reported by BU or BMC Investigators, regardless of funding source.
  • Not student projects for credit or non-federally funded dissertations

• Reporting FCOIs to NIH for PHS-sponsored research, including those of subrecipients

• No funds disbursed until COI review is complete, and FCOI is reported to NIH, if needed
New policy will be launched August 24, 2012!
Applies where the Notice of Award Date is 8/24/12 or later.

Over concern that our institutions were missing the COIs, the government revised its policies to capture more of them.
How will the process change 8/24/12?

1. Investigators disclose $ and do training **online** (paperless)
2. Investigators disclose **more** ($ related to institutional responsibilities)
3. Investigators **update** interests w/in 30 days of a change, and at least annually
   
4. The **ORC**, not Investigators, decides if $ relates to research, and is an FCOI
5. SFI threshold $10,000 minimum → $5,000 + any equity in a private company
How will the process change 8/24/12?

6. **More** information reported to NIH, and more frequent reporting.
   - Information includes nature and value of financial interest, relation to research and management plan

<table>
<thead>
<tr>
<th>Report</th>
<th>Required when?</th>
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<tbody>
<tr>
<td>Initial FCOI Report</td>
<td>Prior to expenditure of funds, or</td>
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<tr>
<td></td>
<td>Within 60 days if SFI is found in ongoing research.</td>
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<tr>
<td>Annual COI Report</td>
<td>Annual report due at same time as when submitting annual progress report or at time of extension.</td>
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<tr>
<td>Revised FCOI Report</td>
<td>After completion of retrospective review, but only if management plan changes, within 120 days after SFI discovery.</td>
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<tr>
<td>Mitigation Report</td>
<td>When <strong>bias</strong> is found as a result of a retrospective review. Report “promptly.”</td>
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<tr>
<td></td>
<td>Bias = actual harm to the research due to the FCOI</td>
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</table>
How will the process change 8/24/12?

7. More research is covered by the new policy

8. BU or BMC, if prime recipient for PHS-funded research, will need to report subrecipient FCOIs to NIH.
   • 64.5% of BU sub-awards and 56% of BMC sub-awards are PHS funded

9. ORC post- management plan decision monitoring and annual check-ins by conflicted Investigators

10. Backward looking retrospective and noncompliance reviews if old financial conflict of interest (FCOI) in ongoing research is found, or management plan isn’t followed

11. Public accessibility – anyone can submit requests for information on FCOIs in PHS-funded research. There will be an online form to submit to ORC.
What has stayed the same?

1. Funds can not be disbursed until the COI review process is done.
2. Associate VP for Research Compliance makes final decision.
3. The basic process.
4. Techniques for managing FCOIs.

(a) Weighing Factors:
- Unique qualifications of Investigator?
- $ nature and magnitude?
- $ is in close relation to research?
- Human subjects?
- Primary site?
- Public perception?

(b) Management Options:
- Disclosure;
- Independent monitor/statistician;
- Modification of the research plan;
- Change of personnel or responsibilities; and
- Reduction/elimination of $.
FCOI Case Process Overview

1. Gather disclosures, compare to research
2. Find Financial Conflict of Interest
3. Committee Review and recommendation
4. Final decision by Associate VP for Research Compliance
5. Management plan compliance by Investigators
FCOI Case Process Overview

ORC monitors compliance with management plans

- Submit copy of signed disclosure letters
- Emails certifying disclosure in presentations, publications
- Report submitted by non-conflicted data analyst
- Independent monitor report
- Audits
- Interviews
- Email inquiries
Education and Advising - Conflicts are Natural

Expertise
- Service on Boards, Panels, Committees
- Industry Relationships
- Inventions

Conflicts of Interest
(actual or perceived)

(Getting in the way of research)
“If I Disclose, Will I get in Trouble?”

Disclosing a conflict of interest does not imply wrongdoing or automatically preclude Investigators from receiving research awards.

BUT...

Undisclosed conflicts can result in serious consequences including loss of research funding and other serious penalties.
Almost 4,000 faculty and physicians  $550 million in grant & contract awards

**BU**
- 2,702 full time faculty
  - 1,240 of them are at the Medical school
  - 1,459 full time administrative, clerical and technical staff
- $425.4 million in grant & contract awards as of 6/30/10
- 1,787 total awards


**BMC**
- 1,290 Physicians
- 791 Residents and Fellows
- $126 million in sponsored research funding in 2010
- 581 research and service projects separate from BUSM.

Disclosure of SFIs related to research (a.k.a. 'Yes' PSDs) by Campus and School

BUMC
- Dental: 4%
- MED: 96%

CRC
- ENG: 40%
- CAS: 60%
Case distribution

CRC research-related SFIs / 'Yes' PSDs by Department

- Mechanical Engineering: 40%
- Chemistry: 30%
- Physics: 20%
- Economics: 10%
“In an observational study there is no human intervention. Researchers simply observe what is happening during the course of events, or they analyze previously gathered data and draw conclusions.”

“...observational studies in general can be replicated only 20% of the time, versus 80% for large, well-designed randomly controlled trials,” says John Ioannidis of Stanford University.

“You can troll the data, slicing and dicing it any way you want,” says S. Stanley Young of the U.S. National Institute of Statistical Sciences. Consequently, “a great deal of irresponsible reporting of results is gong on.”
Conflict of Interest in Research Resources

• BU COI website at: http://www.bu.edu/orc/
  – Policy
  – Implementation guidelines (coming soon!)
  – Training (coming soon!)
  – Forms
  – FAQs (coming soon!)
  – Contact Information

• NIH COI website at: http://grants.nih.gov/grants/policy/coi/

• AAMC COI website at: https://www.aamc.org/initiatives/coi/

Questions?

How to find us:  
**Office of Research Compliance: Conflicts of Interest**  
Boston University  
85 East Newton Street  
Suite M-840, 8th Floor  
Boston, MA 02118


How to reach us:

**Jodi R. Edelstein, JD**  
Compliance Manager  
P. (617) 638-4514  
jedelste@bu.edu

**Leilani Hernandez**  
Compliance Coordinator  
P. (617) 414-4751  
F. (617) 414-4738  
coi@bu.edu