

Identifying and Managing Conflicts of Interest

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Identifying and Managing Conflicts of Interest

- Definition

- A conflict of interest exists when:

- the planning, conduct, or reporting of the research could be affected by the existence of a significant financial interest held by the investigator and/or members of his/her immediate family, or
 - the investigator and/or immediate family members and external entities in which they have a significant financial interest could benefit from the research.

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Case Study

- The university signs a subaward with a company under an NIH contract. Without telling the university, the PI signs a consulting agreement with the company (for closely related work) and uses his graduate students (without paying them) to work on the consulting agreement. The university finds out about the consulting arrangement through a “slip of the tongue” from the company’s President. The subaward contains appropriate provisions for academic freedom, data rights, and other intellectual property rights. The consulting agreement contained the usual consulting terms: company ownership of intellectual property, prior approval of publications, and work performed on a “work-for hire” basis.

cont.

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Case Study cont.

- The PI is also a co-founder of a small business in the same field, and it can be reasonably assumed that the PI's company benefited from his relationship with the other company. The PI did not disclose his relationship with this company to the university.

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Case Study

- **Identify Problems**
 - Lack of Appropriate Disclosure
 - Misuse of Graduate Students
 - Conflicting Terms Between Research and Consulting Agreements
 - Personal Benefits from Both the Consulting Agreement and Possibly Through the Success of His Company

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- Other Examples of Potential Conflicts
 - Company holds license rights to existing or future intellectual property rights of an Investigator that will be affected by the research study;
 - Investigator holds executive position with a Company that stands to benefit from the research study;
 - Investigator holds equity over a certain dollar amount or percentage of a company that stands to benefit from the research study;
 - Investigator receives financial compensation in excess of certain dollar amounts that will be affected by the research study.

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Case Study

- **Conflict of Interest Management Options**
 - Require Appropriate and Complete Disclosure
 - Arrange Payment to Graduate Students
 - Isolate Students From Consulting Work

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Case Study

- **Conflict of Interest Management Options (cont.)**
 - Agreement with PI and PI's Company on Conflict of Interest, Conflict of Commitment, Intellectual Property.
 - Notification of Prime Awardee
 - Agreement with Prime Awardee Regarding Scope or Existence of the Consulting Agreement.

Identifying and Managing Conflicts of Interest

- **Who Might Be Involved in Managing a Conflict of Interest?**
 - Always
 - Conflict of Interest Committee – In Every Case.
 - As Appropriate to the Situation
 - Sponsored Projects Office
 - Department Chair
 - Dean
 - Provost
 - General Counsel
 - Prime Awardee
 - PI's Company
 - IRB

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Federal Context

National Science Foundation (NSF) Policy

http://www.nsf.gov/pubs/policydocs/pappguide/nsf13001/aag_4.jsp

Public Health Service (PHS/NIH) Regulation

<http://grants.nih.gov/grants/policy/coi/>

Federal Drug Administration (FDA) Regulation

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=54>

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Federal Context Purpose of Federal Initiative

From NSF:

“NSF requires each grantee organization employing more than fifty persons to maintain an appropriate written and enforced policy on conflict of interest and that all conflicts of interest for each award be managed, reduced or eliminated prior to the expenditure of the award funds. ” (NSF 13-1, January 2013)

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Federal Context Purpose of Federal Initiative

From PHS:

“The NIH is committed to preserving the public’s trust that the research supported by us is conducted without bias and with the highest scientific and ethical standards. We believe that strengthening the existing regulations on managing financial conflicts of interest is key to assuring the public that NIH and the institutions we support are taking a rigorous approach to managing the essential relationships between the government, federally-funded research institutions, and the private sector.” (<http://grants.nih.gov/grants/policy/coi>)

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Federal Context

PHS Regulation and final NSF policy effective on 10/1/1995;

PHS Regulation and NSF policy were similar in content.

PHS issued a new regulation in 2011 that was effective on 8/2/2012.

New PHS policy is substantially different and more intrusive than the old policy.

BC has created an Addendum to its policy to address the PHS requirements.

<http://www.bc.edu/oric/compliance/conflicts.html>

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Federal Context

The bottom line is that institutions must have conflict of interest policies that take into account and are consistent with relevant federal regulations and policies.

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- The BC Process (cont.)
 - Positive Disclosures
 - OSP sends disclosure to ORIC
 - ORIC Director does initial screen
 - If necessary, ORIC Director sends disclosure to COI Committee for review and discussion
 - COI Committee: VPR, OGC, Directors of ORIC, OTTL, and OSP
 - Note on University Statutes

cont.

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- The BC Process (cont.)
 - Positive Disclosures
 - COI Management Plan
 - See Slides 7, 8, 9, and 10 above

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- ❖ Having a financial interest is not in itself an inherent conflict.
- ❖ Having a financial interest that would reasonably appear to be affected by the research is not in itself a conflict (but such interests must be disclosed).
- ❖ If, however, (1) the planning, conduct, or reporting of the research could directly or significantly be affected by the existence of the financial interest, or (2) the investigator and/or family members and external entities in which they have a significant financial interest could benefit from the research, that must be addressed by the institution according to its policy, consistent with the federal regulations/policy.

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Remember: Public perception of a conflict is sometimes as damaging as the reality of an unmanaged conflict.

Questions?

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