Managing Financial Conflicts of Interest in Research
Promoting Research Objectivity and Maintaining Public Trust

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Office of the Executive Vice President for Research and Partnerships

PURDUE UNIVERSITY
Conflict of Interest

A Conflict of Interest (COI) is any interest, financial or professional that would bias, or appear to bias, objectivity in research, scholarship, and other professional activities.

- **Financial COI**: Occurs when an individual's financial interest influences their professional actions, decisions, or judgment, in pursuing research, scholarship, other professional activities.

- **Professional COI**: Occurs when an individual is an author or a participant in a research project, or has a close professional interest in Investigators conducting a project; or has conflicting professional roles/responsibilities in study (e.g., physician-researcher recruiting research subjects from patient population).
Maintaining Public Trust in Research

Research Related Conflicts of Interest

- Public concerns about industry ties to academia.

- Gene therapy trials (1999): Jessie Gelsinger died; researchers had financial ties to the industry supporting their work and questions were raised about the objectivity of their judgments because of their stake in the trial results.

- Senator Charles Grassley (R-Iowa) launched a Congressional inquiry into conflict of interest from university researchers supported by grants from federal agencies (NIH, NSF, etc.).
Maintaining Public Trust in Research

Research Related Conflicts of Interest (COI) in the media

Dr. Charles B. Nemeroff — Chair of Psychiatry at Emory (at the time):

- Failed to disclose $1.2 million in consulting arrangements with, and COI in clinical trails (sponsored by the National Institutes of Health) of drugs from, Merck, Eli Lilly and Johnson & Johnson.

- Failure to disclose led to NIH suspension of a $9 million grant to Emory (Science Now, Daily News, 14 October 2008).

- Dr. Nemeroff stepped aside from all NIH grants on which he was a PI or Co-PI. He was banned from applying for NIH Grants for a three year period and is no longer at Emory.
Background - Research Framework

**Investigators**
- Comply with University policies and procedures

**Purdue**
- Compliance with award provisions
- Compliance with federal regulations
- Assists and helps Investigators

**Sponsors**
(NIH/NSF/NASA/etc.)

**EVPRP - Office of the Executive Vice President for Research and Partnerships**
FCOI Management - Roles and Responsibilities

**Investigators**
- Disclose SFIs
- Comply with policies

**Company**
- Ownership or other Significant Financial Interest

**Oversight**
- Sponsors (NSF, NIH, NASA, etc.)

**Purdue**
- Design FCOI policy
- Implement policy
- Evaluate SFI
- Identify FCOI
- Manage FCOI
- Report FCOI to federal agencies
- Monitor compliance
- Assist and help Investigators

**EVPRP**
- Office of the Executive Vice President for Research and Partnerships
Promoting Research Objectivity and Maintaining Public Trust

A research related COI must be managed

- Conversion of research results into practical applications (bench to bedside, lab to assembly line) can be positive for all involved: institutions, industry, and the public.

- Public concern that accompanying professional acclaim and financial rewards can serve as a powerful (real or apparent) threat to research objectivity.

- Therefore, a research related COI must be managed. **EVPRP assists and helps researchers manage research related FCOI.**

- If the COI cannot be managed, it must be reduced or eliminated.

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**Basic Principles**

- Universities must establish standards/policies that provide a reasonable expectation that the *design, conduct, and reporting of research will be free from bias* resulting from Investigator/Researcher financial conflicts of interest.

- The University FCOI policy recognizes that researchers may have financial interests in companies with business interests related to their research and requires:
  - Disclosure of financial interests related to research, and;
  - Management of identified Financial Conflict of Interests (FCOI).

- Transparency and openness: *Disclose, Disclose, and when in doubt, Disclose!*

*Office of the Executive Vice President for Research and Partnerships*
 Definitions

- **Investigator** — a person responsible for the design, conduct, and/or reporting of research.

- **Financial Conflict of Interest (FCOI) in research** — a situation in which financial interests of Investigators (and/or their family members) may bias, or have the appearance of biasing, the design, conduct, or reporting of research.

- **Significant Financial Interest (SFI)**
  - Remuneration > $5,000 (from consulting, board membership, etc.)
  - Ownership interest (> 0% in a non-publicly traded company; > 5% in a publicly traded company)
  - Intellectual property (IP) and royalty income from IP owned outside of Purdue/PRF.
Prof. E is a co-owner of a start up company, Innovation Inc. Innovation has licensed a Purdue technology from OTC which it plans to commercialize and further improve. The company was awarded several Small Business Innovation Research grants from NSF and is now sponsoring research in the E lab. Research support in the lab at Purdue also comes from NSF and several other federal agencies and industrial partners. In addition, Innovation has given an unrestricted gift to support research projects and provide financial support for a research assistant. Thesis projects of graduate students in the lab are related to projects sponsored by the company and grants from NIH and NSF.
Issues that may occur/need oversight

- Research objectivity may be compromised due to financial interests (e.g., by choosing to present the results in a way that is most favorable for the business scope of the company).

- Students may feel pressure from the faculty member (real or imagined!) that may lead to bias in the way they conduct their research (e.g., bias in data collection and analysis, reporting of findings).

- Without the knowledge of the faculty member, the student may bias the conduct or outcome of the research in an attempt to please and gain favor with the faculty (e.g., to get good letters of recommendation).
The Case for Research Related FCOI Management

Issues that may occur/may need oversight — Continued

- A faculty member may assign research projects that would advance the business scope of the company but not necessarily the educational goals and needs of the students.

- Research projects sponsored by company are not fully costed and funds from other sources (e.g., NIH, NSF, internal funds) may be allocated to complete company sponsored research projects.

- Complicated situations may arise when graduate students, other trainees, are co-owners of, or employed by, the company.
FCOI Management Plans
A Framework for Managing COI in Academia - Industry Relationships

The Office of the Executive Vice President for Research and Partnerships can help!

FCOI Management Plan (MP):
- Appoints an Oversight Manager (OM), usually the Department Head;
- Describes the specific SFI/FCOI and relationship(s) to Purdue research;
- Requires FCOI training. Investigators with an FCOI are required to complete the FCOI Training tutorial at: http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm and submit a certificate of completion to EVPRP;
- Requires prior approval to engage in a Reportable Outside Activity (https://webapps.ecn.purdue.edu/VPEC).
FCOI Management Plans
A Framework for Managing COI in Academia - Industry Relationships

The Office of the Executive Vice President for Research and Partnerships can help!

FCOI Management Plans (MP) — details (continued)

- Intellectual Property/Technology Transfer and Disclosure: University ownership of IP developed with university resources; transfer of research data only as deliverables from a sponsored project; otherwise, a separate agreement (MTA, NDA, etc.).

- Contracts/Subcontracts and Sponsored Research. Company sponsoring research at Purdue: full costing review.

- Purdue purchases from, or subcontracts to, the company, require prior approval of a Conflict of Interest Disclosure Statement by The Board of Trustees for each Investigator with ownership ties to the company.
Impact on Research Integrity and Students/Trainees

- Disclosure of SFI/FCOI to graduate students, other trainees, and technical staff employed in their Purdue research program; Designate an Ombudsman for each impacted graduate student - a member of the student’s graduate advisory committee who has no association with the company to serve as point of contact for the student and annually certify progress towards satisfaction of degree requirements.

- Disclosure in publications and presentations: the Investigator will disclose his/her relationship with the company in any publication, presentation, or paper submitted for publication, describing Purdue research/outreach activities that overlap materially with the business interests and activities of the company.
Use of University Resources

- University Resources are to be used solely for University purposes and not for personal commercial activities. Company and/or its employees or consultants will not utilize university facilities, equipment, or laboratories in the conduct of company business.
- Research/services can be contracted from the University after the execution of a specific agreement (Research or Testing Agreement, Research Services Agreement, Use of a Recharge Center, other mechanisms specifically made available by the university). Such access will be on a non-interference basis utilizing rates established through standard university business procedures.
- The company will establish and utilize office, research, and development space, postal and electronic mail, and telephone service distinct from those of Purdue University.
Research Related FCOI Management
MP Details — Continued

Annual Review and Reporting to EVPRP

- Each Investigator will meet annually with her/his Oversight Manager(s) to review the requirements of the Management Plan and discuss changes in the Significant Financial Interests, if any.

- The Ombudsmen for the graduate students will submit an annual report of progress towards degree to the Oversight Manager.

- The Oversight Manager will submit a written summary report from the annual review to the Responsible Official in OVPR by June 30th of each year.
Disclosing Research Related SFIs using the (PDD) online application

Each Investigator identified on a research proposal will receive a system generated email message:

Dear VOICHITA DADARLAT,

You are receiving this message because you are a PI/Co-PI, or an Investigator, on the following proposal(s):

**TestNewFIS**
IP# TestNewFIS submitted to PHS-NIH NAT INSTITUTE OF DENTAL RES

Federal regulations and the University policy on Individual Financial Conflicts of Interest (FCOI) require all Investigators (i.e., persons responsible for the design, conduct, or reporting of research) participating in sponsored projects to disclose any Significant Financial Interests (SFI), including SFIs of their Dependents.

Purdue has developed a web based application to collect Financial Interest Statements (FIS) and related disclosures of SFI, when needed. For proposals submitted to NIH or other Public Health Service agencies (PHS), the Investigators must also disclose third party reimbursed and/or sponsored travel related to their Institutional Responsibilities. Several other sponsors, hereafter called PHS-like agencies, have adopted PHS FCOI regulations. FI Statements must be collected and SFI Disclosures must be "Completed", "Updated", or "Up-to-Date", before a proposal can be submitted to the PHS agency or a PHS-like Sponsor.

Please complete and sign electronically your Financial Interest Statement (FIS) online at:

**My Proposals**
The above link will take you to a secure website (https) hosted on an internal Purdue server. To login and sign your form, please use your Purdue Career Account credentials.

Before completing your FIS and corresponding SFI disclosures, please review all relevant definitions (Significant Financial Interest, Institutional Responsibilities and Sponsored/Reimbursed Travel) provided at the website above.

Additional information can be found at: [http://www.purdue.edu/research/vpr/rschadmin/coi](http://www.purdue.edu/research/vpr/rschadmin/coi)
Implementation of FCOI Policy at Purdue

Some Statistics

- Percentage of proposal-based Financial Interest Statements and corresponding Research Related SFI Disclosures reviewed by OVPR for determination of FCOI: ~5.3% (1159 to date since July 1st, 2011).

- Number of active FCOI Management Plans: ~150.

- Ranking of Colleges by the number of FCOI Management Plans (an indication of entrepreneurship/technology transfer activities):
  - College of Engineering,
  - College of Science,
  - College of Agriculture.
Conclusions - Why Disclose and Manage Research Related FCOI

• It is a requirement of the University Policy on FCOI
• Ensures research objectivity and public trust in research
• Protects Investigators from accusations of Conflict of Interest
• Preserves the Investigator and University privileges to apply for, accept, and perpetuate funding from sponsors
• RRSFIDs are subject to Public Record Request laws
• Most journals have their own COI disclosure requirements; the Investigator with a COI Management Plan will be able to indicate that the (real or apparent) conflict is MANAGED by the university.
FCOI Management - Promoting Research Objectivity and Maintaining Public Trust

References and Contacts

- **FCOI Policy: Individual Financial Conflicts of Interest (III.B.2)**
  [http://www.purdue.edu/policies/ethics/iiib2.html](http://www.purdue.edu/policies/ethics/iiib2.html)

- **Table summarizing various COI related processes at Purdue**
  Summary of Research Related Conflict of Interest Forms

- **The FCOI disclosure and management online application:**
  [https://webapps.ecn.purdue.edu/VPR/PDD](https://webapps.ecn.purdue.edu/VPR/PDD)

- **Additional information regarding Disclosure of Research Related Significant Financial Interests can be found on the Conflict of Interest website:**
  [http://www.purdue.edu/research/vpr/rschadmin/coi](http://www.purdue.edu/research/vpr/rschadmin/coi)

- **EVPRP - WE ARE HERE TO HELP/ASSIST/SUPPORT!** For help with research related COI questions, please contact: Voichita Dadarlat [voichi@purdue.edu](mailto:voichi@purdue.edu) and/or Howard Zelaznik, [hnzelaz@purdue.edu](mailto:hnzelaz@purdue.edu), or [fcoi@purdue.edu](mailto:fcoi@purdue.edu).
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Questions?

Comments?

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An electronic version of this presentation can be found at http://www.purdue.edu/research/vpr/rschadmin/coi/docs/FCOIManagement.pdf