

# Managing Financial Conflicts of Interest (FCOI) in Research

## Promoting Research Objectivity and Maintaining Public Trust

Voichita M. Dadarlat, PhD

Office of the Vice President for Research (OVPR)

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# Maintaining Public Trust in Research

## Research Related Conflicts of Interest (COI) in the media:

- ❑ 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

## Example: 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 trials (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.

# 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. **OVPR assists and helps researchers manage research related FCOI.**
- ❑ If the COI cannot be managed, then it must be reduced or eliminated.

# Promoting Research Objectivity and Maintaining Public Trust

## Basic Principles

- ❑ Federal FCOI regulations promote objectivity in research by requiring Institutions to establish standards 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!**

# FCOI Management - Promoting Research Objectivity and Maintaining Public Trust

## 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.

# Background - Research Framework



## Investigators

- Comply with University policies and procedures

**Award**

**Proposal**

**Purdue**



**Sponsors**

(NIH/NSF/NASA/etc.)

- Complies with award provisions
- Complies with federal regulations
- Assists and helps Investigators

**Oversight**



# FCOI Management – Roles and Responsibilities



## Investigators

- Disclose SFIs
- Comply with policies

Ownership or other  
Significant Financial  
Interest

## Company

Contracts

Subcontracts

STIR/SBIR

## Purdue

- Design FCOI policy
- Implement policy
- Evaluate SFI
- Identify FCOI
- Manage FCOI
- Report FCOI to federal agencies
- Monitor compliance with policy/regulations
- Assist and help Investigators



Sponsors  
(NSF,NIH,NASA,etc.)

Oversight



OVPR



# Research Related FCOI Management

## Case Study - Discussion

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 also comes from several federal agencies. In addition, Innovation has given an unrestricted gift to support research projects and provide financial support for a research assistant.

Parts of the thesis projects of graduate students in the lab are related to the projects sponsored by the company and other parts to the scope of grants from NIH and NSF.

# Research Related FCOI Management

## Worse Case Scenarios

- ❑ Research objectivity may be compromised due to financial interests.
- ❑ 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).
- ❑ A faculty member may assign research projects that would advance the business scope of the company but not necessarily the educational needs of the students.
- ❑ Research projects sponsored by company are not fully costed and funds from other sources (e.g., NIH, NSF) 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 Vice President for Research can help!

#### FCOI Management Plan (MP) – details:

- ❑ 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 OVPR;
- ❑ 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 Vice President for Research 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.

# Research Related FCOI Management

## MP Details - Continued

### Impact on Research Integrity and Students/Trainees

- ❑ **Disclosure of SFI/FCOI** to graduate students, other trainees, and technical staff employed in Investigator's 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.

# Research Related FCOI Management

## MP Details - Continued

### 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 only after the execution of a specific agreement (Research or Testing Agreement, Research Services Agreement, or Use of a Recharge Center). 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 OVPR

- 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 30<sup>th</sup> of each year.

# 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: 4.4% (400 to date since July 1<sup>st</sup>, 2011).
- ❑ **Number of FCOI Management Plans:** ~90.
- ❑ **Colleges with most FCOI Management Plans:**
  - ❑ College of Engineering,
  - ❑ College of Science,
  - ❑ College of Agriculture.



# FCOI Management - Promoting Research Objectivity and Maintaining Public Trust

## References and Contacts

- ❑ Purdue's FCOI Policy: **Individual Financial Conflicts of Interest (III.B.2)**  
<http://www.purdue.edu/policies/ethics/iiib2.html>
- ❑ Additional information regarding Disclosure of Research Related Significant Financial Interests can be found at OVPR's Conflict of Interest website:  
<http://www.purdue.edu/research/vpr/rschadmin/coi>
- ❑ **OVPR - WE ARE HERE TO HELP/ASSIST/SUPPORT!** For help with research related COI questions, please contact: Dr. Voichita Dadarlat [voichi@purdue.edu](mailto:voichi@purdue.edu) and/or Dr. Howard Zelaznik, [hzelaz@purdue.edu](mailto:hzelaz@purdue.edu), or [fcoi@purdue.edu](mailto:fcoi@purdue.edu).

Questions?

Comments?

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