Management of Research Related Conflicts of Interest

Protecting Research Objectivity, Research Subjects, and Public Trust in Research

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Office of the Executive Vice President for Research and Partnerships

Origins of Conflicts

Purdue – a complex, inter-connected ecosystem whose mission is to serve IN, US, and the world through **discovery**, **learning**, and **engagement**.

Employees – for many, professional and personal lives are completely separate, but in some cases there may be overlap between outside interests and Purdue responsibilities that involve **time commitment** and/or **financial interests** in activities such as:

- Outside consulting/employment
- Entrepreneurship/Licensing of technologies by start-up companies
- Conflicting professional and fiduciary responsibilities.

These situations may lead to **CONFLICTS**!

Types of Conflicts

❑ **Conflicts of Commitment (COC)** – may occur when employees engage in outside activities; a full-time Employee's primary professional or occupational commitment is to the University.

❑ **Financial Conflicts of Interest (FCOI)** – may occur when Employees' Financial Interests may bias, or could appear to bias, their judgment or ability to carry out their Purdue responsibilities. An FCOI may be related to research and/or purchasing/procurement or sub-contracts.

❑ **Nepotism** – occurs when there is a Supervisor/Supervisee or a PI/CO-PI/Investigator (family) relationship (Policy II.B.3).

Financial Conflicts of Interest (FCOI)

Management of Financial Conflicts of Interests - guided by the Purdue Policy on Individual Financial Conflicts of Interest (III.B.2)

FCOI may be related to:

- **Research** – FCOI managed by EVPRP/SPS/Regulatory Committees (IRB, PACUC)

- **Purchase/Procurement** – FCOI managed by Procurement/Purchasing Services and the Office of the Vice President for Ethics and Compliance (VPEC).

Research Related FCOI – Why do we care?

Protect, preserve, and advance the discovery mission of the University

- Non-compliance with federal/state regulations and ethical rules on FCOI, may lead to a total or partial ban on applications for federal and state funding.

- Compliance with FCOI rules preserves the university ability to continue to apply and receive funding for research.

Protect Faculty/Investigators from unfounded accusations of Conflict of Interest

- Investigators are required to **disclose** and **manage or eliminate** their outside financial interests.

- Purdue provides tools, assistance and guidance.

Research Related FCOI - Origins

External Financial Interests

May arise from activities such as:

- Entrepreneurship/faculty start-up companies

- Licensing of Purdue technologies

- Financial rewards/remuneration due to outside consulting and/or employment.

Research Integrity

May impact:

- Research objectivity

- Data Integrity

- Safety and welfare of human and animal subjects

- Students/Trainees/Collaborators.

The risks must be assessed and the FCOI must be Managed or Eliminated by the University and Investigators.

RR-FCOI Management - Roles and Responsibilities

Investigators

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

Ownership or other Significant Financial Interest

Company

Contracts

Subcontracts

STTR/SBIR

Purdue

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

EVPRP

Sponsors

(NSF,NIH,NASA,etc.)

Oversight

EVPRP - Office of the Executive Vice President for Research and Partnerships

Practical Implementation of Research Related FCOI Management at Purdue – the PDD

PDD = Proposal Driven Disclosure online application

How does it all work?

Current Users and their Responsibilities:

- SPS Pre-Award + Technical Support – enter proposal information, including all Investigators in the PDD (twice a day SPS file upload; manual addition is available, if needed).

- SPS Pre-Award managers ensure that proposals are "Submission Ready" before submission of a proposal to an external sponsor.

PDD Users: Researchers/Investigators

Investigator Actions:

- Fill out a Financial Interest Statement (FIS) for each proposal

- IF SFI, fill out RRSFIDs

- IF proposal to DHHS/NIH, submit FCOI Training certificate

- If RRFCOI, review and sign the FCOI Management Plan.

Data Entered in the PDD

- Answers to YES/NO FI question

- Complete RRSFID by entering details about the company and research program at Purdue

- Complete and submit FCOI Training certification - valid for 4 years.

PDD Users – Post Award Managers

Post-Award Actions:

- Check the specific project record to ensure that the project is "Award Ready" (i.e., all RRCOI requirements are completed).

- If not, update the Award Status for the project to NOA/NTP/JIT.

- The PDD generates notifications to Investigators on the project who have not completed all requirements

- When requirements completed and the project becomes "Award Ready", the system sends notification to SPS Post-Award.

Data Entered by Post-Award Managers:

- At NOA/NTP/JIT if Project is not "Award Ready", update the project status; system sends notifications to Investigators who have not completed all FCOI requirements

- Project Start and End Dates

- Additional Investigators, if identified at award time.

PDD Users - COI Managers and the Responsible Official

PDD Actions:

- Review RRSFIDs and make RRFCOI and "relatedness" determinations

- Draft and execute an FCOI Management Plan

- Review each project with YES FI Statements and make project specific COI determination.

- If project sponsored by DHHS/NIH, submit an FCOI Report to NIH and an annual report of Compliance

- Request and collect Annual Reports of Compliance with the MPs from Oversight Managers/Dept. Heads

Data Entered

- Project/Investigator specific COI Status

- Add/Deactivate Investigators, as needed

- Add FCOI Training information for each Investigator on DHHS/NIH awards

- Project based COI Reviews

- FCOI Management Plans - draft, negotiate and route for signatures

FCOI Management Plan

What is an FCOI Management Plan (MP)? What does it do?

- An MP is an executed agreement between the Employee/Researcher with financial interests and the University that outlines the conditions for FCOI management, including the handling of IP, notifications of students/collaborators, use of university facilities, requirements of other applicable PU policies (e.g., disclosure of FI prior to purchasing/procurements from company, etc.)

- It appoints an Oversight Manager (usually the Department Head) to provide oversight and (at least annual) review of the employee activities with the company.

- The Oversight Manager is required to submit an Annual Report of Compliance with the MP to the University Responsible Official or VPEC.

FCOI MP Information Sharing with Business Offices

- EVPRP shares the lists of Active MPs semi-annually with SPS, VPEC, Purchasing/Procurement and any other units with a demonstrated business need.

- Each PU Department/College has, or should keep records of approved MPs for Researchers/Faculty in their respective units as the MPs are signed by Dept. Heads and Deans before coming to EVPRP.

- Access to information available in the PDD is granted by request to all PU individuals with a demonstrated business need.

- In addition, business offices and other units may request lists of all approved Conflicts of Interest Disclosure Statements from the COI Officer/VPEC, as needed to fulfill their business needs.

Research Related FCOI Management

A Case Study

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 both projects sponsored by the company and grants from NIH and NSF.

Useful Resources – Guidance for Investigators and their Business Offices

Guide to securing required approvals and manage conflicts of commitment and financial conflicts of interest:

https://www.purdue.edu/research/research-compliance/conflict-of-interest/docs/disclosure%20june%202016.pdf

Conclusions

Why 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.

Managing FCOI and COC – VPEC and EVPRP Resources

VPEC Resources: http://www.purdue.edu/ethics/resources/conflicts.html

VPEC Contacts:

- vpec@purdue.edu

- compliance@purdue.edu

EVPRP Resources:

https://www.purdue.edu/research/research-compliance/conflict-of-interest

EVPRP Contact: fcoi@purdue.edu

Thank you for your attention!

Questions?