

Management of Conflicts of Interest and Commitment - a Shared Responsibility -

Guidance for Purdue University Leaders



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**Office of the Executive Vice President for Research and Partnerships
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Research Framework: *Before* the Bayh-Dole Act



Investigators

- * Comply with PU policies and award rules

1980: The Bayh-Dole Act - universities retain title to inventions, patents & licensing IP

Proposal

Purdue



VPR (now EVPRP)

- * Assist Investigators
- * Submit invention disclosures to sponsors

Award

Sponsors
(NIH/NSF/NASA/etc.)



Research and Entrepreneurship: *After* Bayh-Dole



Investigators

- * Engage in entrepreneurship & consulting
- * Disclosure of financial interests / outside activities

Companies

Proposal

Purdue



- **Retains IP (via PRF/OTC)**
- **Implements policies for managing Conflicts of Commitment (COC) and Financial Conflicts of Interest (FCOI) via EVPRP and VPEC (Vice President for Ethics and Compliance)**

Award

Sponsors
(NIH/NSF/NASA/etc.)



Contracts
Purchases

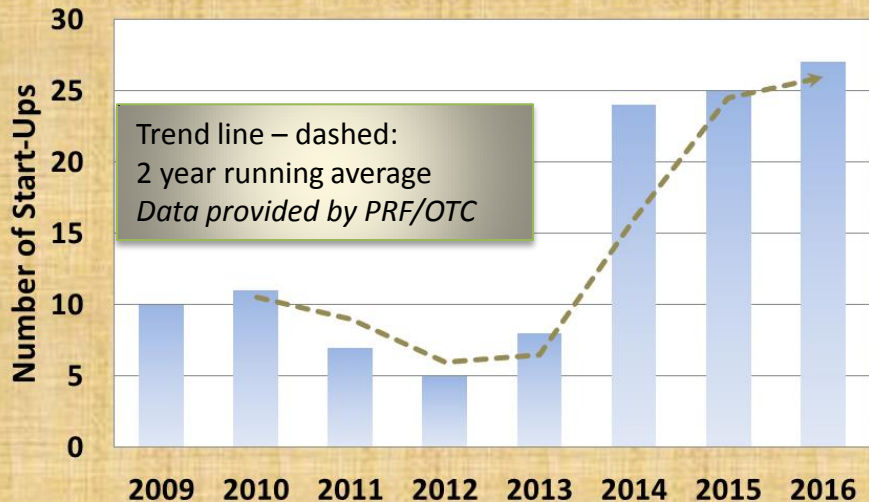
STTR/SBIR

Agreements
Licensing

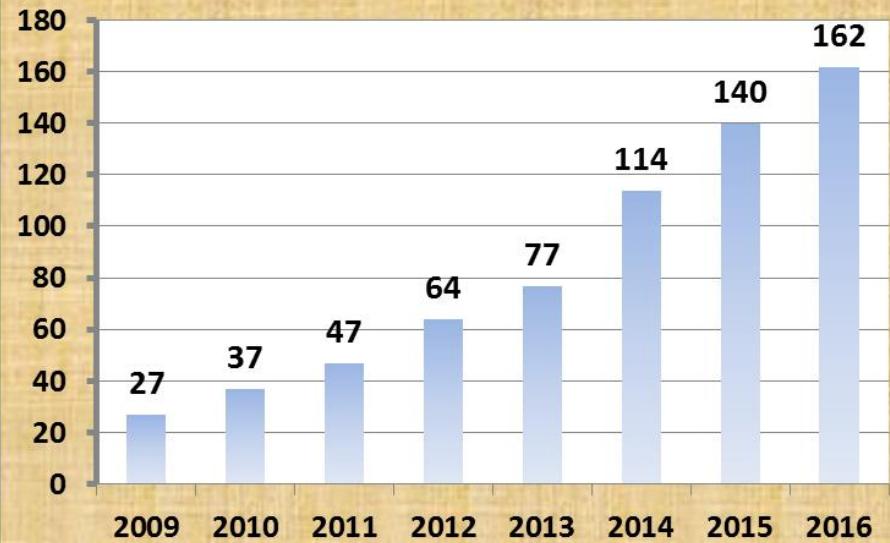
PRF/OTC

Purdue as “Entrepreneur U.”

Number of Start-up Companies Based on Purdue Innovations by Fiscal Year



FCOI MPs per Fiscal Year - Cumulative



❑ **Tech transfer activity** (based on a formula that includes patents issued, licenses executed, licensing income and startup creation): Purdue ranks No. 1 in the Midwest, No. 1 nationally among public institutions without a medical school and No. 12 overall (from *Purdue Research Foundation News*, April 20, 2017)

❑ **EVPRP: ~200 Active FCOI Management Plans (7x increase in the last 8 years)**

Types of Conflict

Conflicts of Commitment (COC) – arise when commitment towards outside activities interferes with the Employee's ability to fulfill their commitment to the University

Financial Conflict of Interest (FCOI) – situation where an Employee's actions at the University could lead to financial gain for the Employee or their Dependents

FCOI – may materialize in research, procurement, acceptance and use of gifts to the university/ research programs, committee membership/voting and other institutional decisions

Nepotism: may occur in hiring, supervision

Professional COIs (*a topic for another presentation...*)

Time Commitment and ROAs

Reportable Outside Activities

Any work, advice, or service for an entity other than Purdue, such as:

- participation in any business enterprise, service as an officer/director
- serving as a faculty member at other schools or universities
- consulting and/or conducting external research
- service on an advisory council or scientific advisory board of a company or organization, etc.,

is a Reportable Outside Activity (ROA) and must be disclosed and approved

Time Commitment

- **Tenured and tenure-track Faculty**: during the term of their academic appointment, the average time dedicated towards all ROAs **must not exceed one business day per week**. Exceeding this time limit may constitute a Conflict of Commitment (COC)
- **All other Employees**: must complete all their outside activities **outside of university business hours**, or using weekends, vacation, or unpaid leave

COC/ROA Policy

Roles and responsibilities

Employees: **disclose** ROAs and obtain **prior approval** from their Dean/Unit Head

Department Heads/Supervisors: **evaluate** requests and **recommend** for approval/denial by the Dean/Unit Head

Deans/Unit Heads: evaluate and **approve, deny, or elevate** to the Outside Activities Officer (OAO) in the Office of the Vice President for Ethics and Compliance (VPEC); currently Deb Trice serves as the OAO

Tools

Outside Activities Disclosure dedicated online application:
<https://webapps.ecn.purdue.edu/VPEC/OAD/>

Tips for Evaluating ROA Requests

Contemplated outside activities should align with, and enhance, the goals and mission of the Department/College/Unit and the University

Department Heads and Deans can always ask the employee to “Withdraw” and re-submit the ROA request if additional information is needed to evaluate it

Deans/Unit Heads can consult with Department Heads or the Outside Activities Officer (OAO) before approving an ROA, or elevate the ROA request to the OAO’s attention

Examples of Research-related FCOIs

Receiving consulting fees from, and **owning stock** in, a company while performing research on the company's technology

Conducting federally-funded research that could affect the financial interests of a company in which the Investigator has a personal financial interest

Involving students or post-docs and other trainees in work that could directly benefit a company in which the advisor/faculty member has a personal financial interest

Giving a company preferential access to results of university-conducted research while having an ownership interest in, or providing personal consulting services to, that company

FCOIs and Institutional Responsibilities

- **FCOIs in purchasing/procurement** from employee-owned companies; **require prior approval from the Board of Trustees**, an executed FCOI Management Plan, and an approved outside activity
- **FCOIs related to gifts** received by researchers with financial interests from affiliated entities; **require** the execution of a Management Plan (the gift account will be at the discretion of the Department Head; no salary, travel, or other benefits, for the researcher with financial interests in the donor)
- **Participation in institutional decisions about products/services** offered by a company in which the employee holds ownership interest; **requires recusal** from decision making

Financial Interests – Definitions

Financial Interest – Any interest that will, could or is intended to lead to a profit or an increase in the income or net worth of an Employee, Investigator and/or a Dependent; through the receipt of payments of any kind (e.g., salary, consulting fees, honoraria, gifts, dividends, distributions, rent, paid authorship, etc.), equity Interests, an increase in the value of real estate or Equity Interests, or Intellectual Property Rights

Investigator – a person responsible for the design, conduct, or reporting of research

Significant Financial Interests (SFIs) – Financial Interests held by Investigators and/or an Investigator's Dependent that reasonably appear to be related to the Investigator's Institutional Responsibilities such as:

- **Remuneration** (including salary, consulting fees, honoraria, paid authorship and travel reimbursement) received **from a publicly traded company** during the twelve-month period preceding the date of the disclosure, and/or an Equity Interest in a publicly traded company, if the aggregate value of such remuneration, plus the value of the equity **exceeds \$5,000**
- **Remuneration > \$5,000** received from a **non-publicly traded company** during the twelve-month period preceding the date of the disclosure
- **More than five percent Equity Interest or ownership in a publicly traded company** or business
- **Any Equity Interest in a non-publicly traded company** or business, regardless of value
- **Intellectual Property Rights**, regardless of value, **upon receipt of income related to such rights**
- For **proposals submitted to and/or awards received from PHS/NIH agencies**, any **third party reimbursed or sponsored travel**; travel sponsored by a federal, state or local government agency, an institution of higher education, an academic teaching hospital, a medical center or research institute affiliated with an institution of higher education **does not need to be disclosed**

FCOI Management

- **Researchers/Investigators*** fill out a **Financial Interest Statement** (FIS, a YES/NO question regarding private financial interests) when they submit proposals to sponsors or protocols to IRB/PACUC
- **Investigators with Significant Financial Interests (SFIs)** disclose those interests on a **Research Related SFI Disclosure (RRSFID)**
- **Employees who are founders** of start-ups based on PRF-owned technologies disclose **related SFIs** at licensing
- **EVPRP evaluates** disclosures and, in conjunction with the Investigator, makes a Financial Conflict of Interest (FCOI) determination (i.e., is there a real or apparent FCOI?)
- **EVPRP evaluates FCOIs related to sponsored research projects** and submits FCOI reports to federal agencies and other sponsors, as required by federal regulations

FCOI Management

If a real or apparent **FCOI is identified**, a Management Plan (MP) is executed, as follows:

- **EVPRP** → Drafts the plan
- **Investigator** → reviews, accepts, and complies with, the MP
- **Oversight Manager** → signs the plan and monitors compliance
- **Unit Head** → signs the plan, provides college level oversight

Tools: SFI disclosure and FCOI management online application: <https://webapps.ecn.purdue.edu/VPR/PDD>

FCOI Management Plan

- A **framework** for managing FCOI in academia - industry relationships
- Appoints an **Oversight Manager** (OM), usually the **Department Head** and describes the specific FCOI and relationships to Purdue research
- Requires **FCOI training** and prior approval to engage in a Reportable Outside Activity, as needed

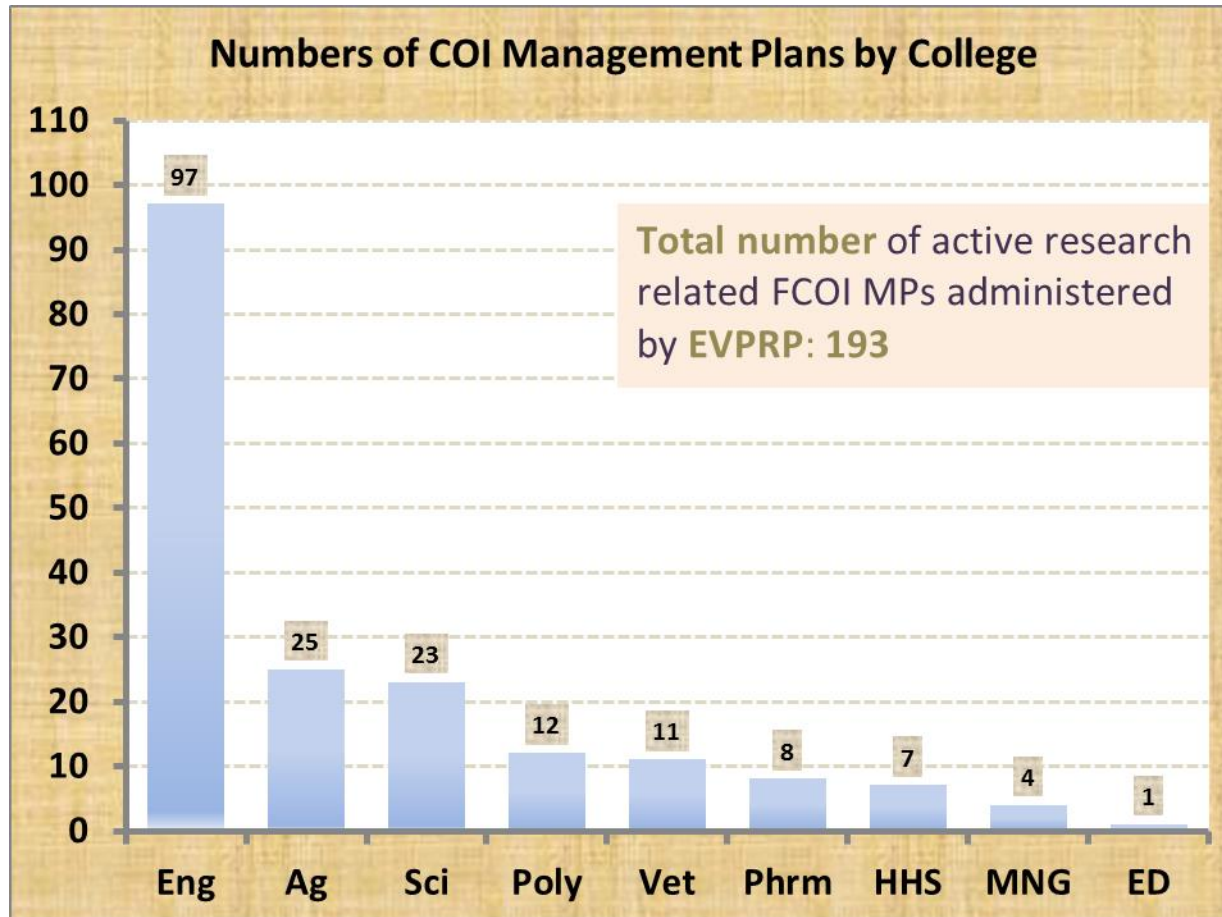
FCOI Management Plan Provisions

- **Intellectual Property (IP), Technology Transfer and Disclosure:** University owns IP developed with university resources; transfer of research data only as deliverables from a sponsored project; otherwise, a separate transfer agreement
- **University Resources** are to be used solely for University purposes; 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 (e.g., research, testing, or services agreement, use of a recharge center) other mechanisms specifically made available by the university

FCOI Management Plan Annual Review

- **Investigators** with FCOIs meet annually with their Oversight Manager(s) to review the requirements of the MP and discuss changes in their Financial Interests
- **The Oversight Manager submits a report of compliance** to the Responsible Official in EVPRP by the end of each fiscal year

FCOI MPs Administered by EVPRP



Tip: Department Heads and Deans can always review FCOI MPs for their Faculty at:
<https://webapps.ecn.purdue.edu/VPR/PDD/ptManagementPlanLanding>

Why Care about FCOI Management?

- **It is a requirement of the University Policy** on FCOI, federal and state regulations; promotes research objectivity, maintains public trust in research, promotes good stewardship of University resources
- **Protects Investigators from unfounded accusations** of Conflict of Interest; preserves Investigator and University privileges to apply for funding from sponsors
- **Federal agencies and academic journals** have specific COI disclosure requirements; Investigators are able to indicate that conflicts are managed by the university

Consequences of Non-Compliance

- **Individual faculty/researcher:** impact on reputation, research funding, and/or employment status
- **University:** Impact on the privilege to apply for, and receive, federal funding for research, impact on reputation
- **FOIA requests:** SFI/ROA disclosures are subject to open record laws
- **Heightened interest** from the general public, journalists, and colleagues, especially when a company/technology becomes very successful

A Shared Responsibility

Questions?

- Contact fcoi@purdue.edu for questions regarding research related SFI disclosure, FCOI Management, and purchases of scientific equipment from, or sub-contracts for research services to, faculty/employee-owned companies
- Contact vpec@purdue.edu for questions regarding FCOI in Purchasing, Gift Acceptance, Nepotism, and ROA disclosures

Comments?

- Please send your comments and suggestions about this presentation to voichi@purdue.edu or fcoi@purdue.edu