

*Managing
Conflicts of Interest in Research and
Entrepreneurship - A Shared Responsibility*



Voichita M. Dadarlat, PhD
Assistant Vice President for Research

Office of the Executive Vice President for Research and Partnerships
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PURDUE
UNIVERSITY

Be Bold, Innovate, Invent, Impact!

- Purdue “fosters a culture of entrepreneurship that extends from the newest freshman on campus to the most senior faculty member. If you have a great idea, Purdue is the place to develop what's in your mind and take it to the market.”

Mitch Daniels, President of Purdue University, press release February 8, 2013

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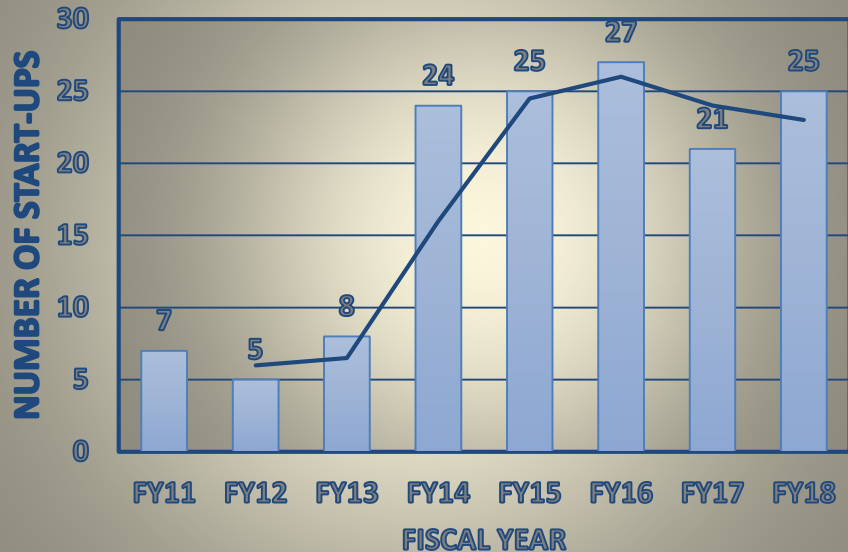
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- Purdue aims to “build the nation’s best ecosystem for innovation and entrepreneurship”

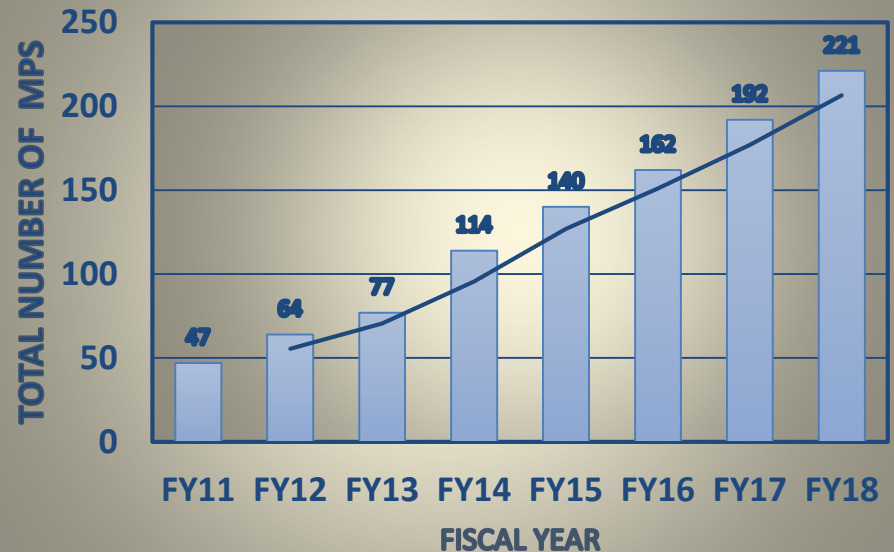
Mitch Daniels, “5 years, 60 startups: Purdue students own their inventions, thriving under university’s policy”, press release, September 6, 2018

Purdue as “Entrepreneur U.”

Number of Start-ups per 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). 142 new start-up companies in the last 8 years.
- ❑ **EVPRP: > 230 Active FCOI Management Plans.**

Research Landscape: *Before* 1980



Researchers/Investigators

- Comply with PU policies and award rules

Proposal

Purdue



VPR (now EVPRP)

- Assist Investigators
- Submit invention disclosures to sponsors

Award

Sponsors
(NIH/NSF/NASA/etc.)



A Change in Landscape: 1980



Investigators

- Comply with PU policies and award rules

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

Proposal

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**1980 Bayh-Dole and Stevenson-Wydler Acts, 1986 Federal Technology Transfer Act*

Research and Entrepreneurship: *After* Bayh-Dole



Investigators

- Engage in entrepreneurship & consulting
- Disclose financial interests and outside activities

Companies

Proposal

Purdue



Contracts
Purchases

STTR/SBIR

Agreements

Licensing

PRF/OTC

Sponsors

(NIH/NSF/NASA/etc.)

Award



Issue FCOI regulations, ensures research objectivity and public trust in research

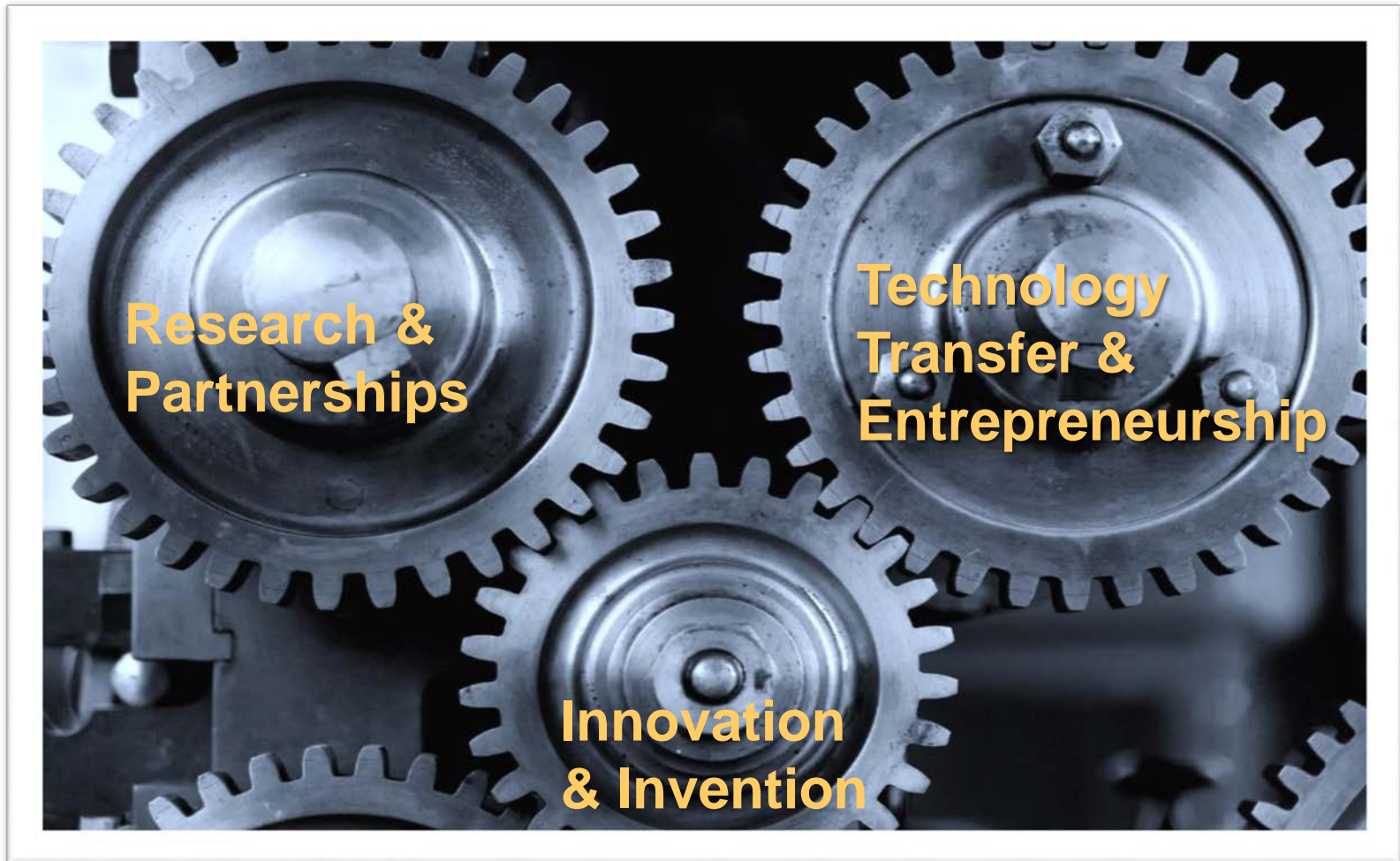
- **Retains IP (via PRF/OTC)**
- **Implements policies for managing Conflicts of Commitment (COC) and Financial Conflicts of Interest (FCOI) via EVPRP and VPEC (Vice President for Ethics and Compliance)**
- **End goals: Protect, preserve, and advance the discovery and technology transfer missions**

EVPRP/COI

Mission Statement

Our office works to promote and maintain research objectivity and public trust in research and entrepreneurial activities based on intellectual property developed at Purdue. We assist the university community in finding appropriate research and collaborative frameworks that ensure ethical and productive engagement of faculty– and student– entrepreneurs with their industrial partners. We reduce administrative burden by creating modern tools for disclosure and management of research related financial conflicts of interest (FCOIs).

Moving the World Forward



Moving the World Forward, Mindfully



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, gifts to the university and research programs, committee membership and voting, institutional decisions, [technology transfer and IP ownership](#)

Nepotism: may occur in hiring, supervision

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

Examples of Research-related FCOIs

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

Conducting research that could affect the financial interests of a company in which the Investigator has a personal financial interest; involving students and trainees in work that benefits a company in which the advisor/faculty member has a financial interest

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

Transfer of technologies/IP and data/materials without a properly executed licensing or transfer agreement

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
- **Outside 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 – Overview

Researchers disclose **Financial Interests** at proposal and protocol submission, before procurement, and/or annually (**EVPRP, SPS, IRB, VPEC**)

Employees who are Founders of start-ups disclose **SFIs** at licensing (**Foundry, OTC, EVPRP**)

EVPRP evaluates disclosures and makes a Financial Conflict of Interest (FCOI) **determination: Is the FCOI Manageable?**

IF YES → Management Plan

IF NO → Reduce SFIs/evaluate again or eliminate conflicts

EVPRP evaluates FCOIs for each project and submits reports to sponsors

Researchers disclose associated financial interests/COIs in publications and presentations, to students and trainees, to collaborators

Oversight Managers/Department Heads monitor activities and submit an Annual Report of Compliance to EVPRP

FCOI Management Plan Provisions

- **Intellectual Property, 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

Special Topic: IP Developed During Outside Activities

- Recent guidance on handling IP developed in approved outside activities:

<https://www.purdue.edu/research/regulatory-affairs/intellectual-property-faq.php>

- SFI: Income received from IP rights developed as part of approved outside activities and/or during prior employment (if **related** to institutional responsibilities at Purdue)
- Discussion and input from OTC

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 Entrepreneurs and their companies from unfounded accusations** of Conflict of Interest; preserves Investigator, University and company privileges to apply for funding from sponsors
- **Federal agencies and academic journals** have specific COI disclosure requirements; authors are able to indicate that conflicts have been disclosed and are managed by the university

Consequences of Non-Compliance

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

Case Study: FCOIs at Memorial Sloan Kettering Cancer Center (MSK)

Pro-Publica and NYT Investigation and fallout at MSK, Sept. 2018:

- [Top Cancer Researcher Fails to Disclose Corporate Financial Ties in Major Research Journals](#)
- [Top Sloan Kettering Cancer Doctor Resigns After Failing to Disclose Industry Ties](#)

Headline: *“One of the world’s top breast cancer doctors failed to disclose millions of dollars in payments from drug and health care companies in recent years, omitting his financial ties from dozens of research articles in prestigious publications like The New England Journal of Medicine and The Lancet...”*

Dr. José Baselga, chief medical officer and physician-in-chief at MSK, resigned... amid reports that **he had failed to disclose millions of dollars in payments from health care companies** in dozens of research articles; sat on the board of the drugmaker Bristol-Myers Squibb and Varian Medical Systems, a manufacturer of radiation equipment”

A Prominent Career, Derailed

José Baselga is the lead author on successful clinical trials and associated publications

- BOLERO-2: found a significant progression-free survival (PSF) benefit for combining Afinitor with exemestane in postmenopausal women with estrogen receptor-positive, HER2-negative metastatic breast cancer
- CLEOPATRA: established a PFS benefit for using the novel therapeutic pertuzumab with trastuzumab (Herceptin) as a dual HER2 blockade for HER2-positive patients with late-stage disease
- NeoALTTO: found that administering lapatinib (Tykerb) plus trastuzumab in the neoadjuvant setting for HER2-positive patients produced a significant advantage in pathologic complete response.

JB “Defense”: misunderstanding of reporting requirements; Dr. Baselga indicated that he “believed” that he only had to disclose payments from companies with FDA approved drugs and/or devices

Case Study: Fall-out

MSK COI Investigation fall-out (part I):

- Dr. Craig B. Thompson, the chief executive of Memorial Sloan Kettering Cancer Center ... will resign his seats on the boards of drug maker Merck and other public companies, the latest fallout from a widening institutional reckoning over relationships between cancer center leaders and for-profit health care companies
- Dr. Thompson has served on the board of Merck, the maker of the blockbuster cancer drug Keytruda, since 2008. He has been on the board of Charles River Laboratories, a publicly traded company that assists research in early drug development, since 2013. He received \$300,000 in compensation from Merck in 2017, [according to company financial filings](#). He was paid \$70,000 in cash by [Charles River](#) in 2017, plus \$215,050 in stock

Case Study: Fall-out

MSK COI fallout (part II):

- Dr. Gregory Raskin - vice president at MSK was a member of the board of a startup company, Y-mAbs Therapeutics. In 2015, he signed off on a company deal with MSK, where the company's experimental treatments for children with cancer have been developed. Dr. Raskin received a stake of nearly \$1.4 million in Y-mAbs for representing the hospital on its board. **He is giving back to MSK his stake in the company.**

Sloan Kettering's Cozy Deal With Start-Up Ignites a New Uproar

- Dr. David Klimstra, the chairman of the Pathology Department at MSK is **divesting his equity stake** in Paige.AI, an artificial intelligence company. Paige.AI has signed an exclusive licensing deal with MSKCC for digital images of 25 million tissue slides." **Company founders are MSK executives and the deal was perceived as benefitting the company but not MSK.**
- **MSK Task Force on COIs, review and change in policies**
- **Concerns from patients, employees ("MSK mission compromised!"), congressional representatives**

Some Lessons:

1. **Disclose, disclose, and when in doubt, disclose!**
2. **Clarify roles, missions, and fiduciary responsibilities**

Resources for Navigating the COI Landscape

- Employee decision tree (COI/COC):
<https://www.purdue.edu/research/regulatory-affairs/conflict-of-interest/docs/disclosure%20june%202016.pdf>
- SFI/FCOI disclosure and management online application:
<https://webapps.ecn.purdue.edu/VPR/PDD>
- Outside Activities Disclosure dedicated online application:
<https://webapps.ecn.purdue.edu/VPEC/OAD/>

Useful Resources

Contracting with the University:

- Research or testing agreements - contact the Contracting group in SPS at spscontr@purdue.edu; or (765) 494-3863. Additional information on how industrial partners can contract with Purdue at:
<https://www.purdue.edu/business/sps/contractmgmt/index.html>
- Use of established recharge centers:
<http://www.purdue.edu/business/mas/costing/iLab/index.html>

Relevant Policies:

- Individual Financial Conflicts of Interest (III.B.2)
<http://www.purdue.edu/policies/ethics/iiib2.html>
- Conflicts of Commitment and Reportable Outside Activities (III.B.1)
<http://www.purdue.edu/policies/ethics/iiib1.html>
- Intellectual Property (I.A.1)
<http://www.purdue.edu/policies/academic-research-affairs/ia1.html>

FCOI Management - A Shared Responsibility

- Employees, VPEC, EVPRP, SPS, OTC, Foundry, Procurement, Departments, Colleges -

Questions?

- Contact fcoi@purdue.edu for questions regarding FI disclosure at licensing, FCOI Management, and purchases of scientific equipment from, or sub-contracts for research services to, employee-owned companies

Comments?

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