

Approaches to managing Conflicts of Interest at Cornell

Research Case Studies

Developed by:

Emmanuel Giannelis, Vice Provost for Research and Vice President for

Technology Transfer, Intellectual Property, and Research Policy

Amita Verma, Director, Office of Research Integrity and Assurance

Purpose

Use real case studies to illustrate the approach taken by the Cornell Financial Conflict of Interest Faculty Committee (FCOIC) to address situations that present *real* or *apparent* conflict of interest related to research



Overarching principles

- 1. Support faculty entrepreneurship, support industry engagement
- 2. Meet sponsors, public, regulatory, legal requirements
- 3. Preserve research integrity
- 4. Protect academic freedom
- 5. Protect human participants
- 6. Protect interests of students and staff
- Conflicts are a set of intersecting relationships
- Conflicts are not bad
- Most conflicts can be managed



Case Studies

- Faculty consulting
- 2. Faculty invention licensed to their company
- 3. Direct funding from a faculty-owned company
- 4. Faculty-student business partners
- Faculty Start up funding SBIR Phase I



Case 1: Faculty consulting

Noah Brown, Professor in Chemical Engineering.

- Expert in food safety
- Consults for FoodSafety Inc. which develops food safety testing technology
- Situation #1: Noah receives no research funding or gifts from FoodSafety
- Situation #2: Noah's wants his GRA to work with him on the consulting project
- Situation #3: FoodSafety Inc. awards a grant to Cornell with Noah as the PI



Case 1: Faculty Consulting

- Situation 1: No company funding: No Conflict; Guidance on External Relationships
 - Disseminating knowledge is part of the academic mission, and encouraged
 - Noah should separate his consulting activities from his research
 - no Cornell resources are used for consulting
 - separation of IP in the consulting agreement
 - Cornell University Guidance on Consulting and Other External Engagements by Faculty

- Situation 2: Student as co-consultant: student involvement not allowed
 - Faculty may not involve their current students in their outside activities. Exceptions with approval from DGS or Special Committee



Case 1: Faculty Consulting

- Situation 3: Funding from a company in which the faculty have a financial interest presents an allowable COI that can be managed
 - A management plan is developed with these terms:
 - Disclosure to students, publications, collaborators
 - Clarity regarding scope of work related to the company
 - Sponsored project terms similar to any industry sponsored project
 - Appointment of a conflict manager (Department Chair)
 - Conflict manager checks in annually with students



Case 1: Consulting and human subjects research

Situation 4: Noah now also serves on the board of FoodSafety Inc. He wants to conduct human participant research on the effect of product messaging developed by FoodSafety Inc.

Policy:

"Rebuttable presumption": Research personnel who are involved in the design,
participant selection, informed consent process, or conduct of a study with human
participants cannot have a financial interest in an entity whose interest could be affected
by the research.

Committee's Decision:

This situation presents a significant conflict that cannot be managed.



Case 2: Faculty Invention licensed to their company



Image Source: http://ualr.edu/techlaunch/home/technology-development-and-licensing/

Ling Chin, Professor of Computer Science

 Invention allows one to identify the location of a geographical landmark from an image.



http://workinginpeelhalton.com/

- Starts "Find Pic" to license the technology from Cornell
- NSF funded research in related areas
- Plans to continue research at Cornell



Case 2: Chin and "Find Pic"



- Under what conditions should this be allowed?
- Should NSF be informed?



Case 2: Chin and "Find Pic"

A Conflict of Interest that can be managed with a standard plan

- Chin's Department Chair is appointed as a "Conflict Manager"
- Disclosure to students and staff, collaborators on related research, & publications
- No university resources may be used to conduct company business
- Chin's current students or staff cannot also work for the company
- A license to the company issued only after the COI requirements are met

http://www.nature.com/naturejobs/2017/170323/images/1.jpg



Case 3: Faculty company directly funding faculty research

Amanda Smith, Assistant Professor at the Vet School

- Invented a genetic testing toolkit for cats; started a company
 "Pawgenes"; Pawgenes has licensed IP from Cornell
- Pawgenes doesn't have lab space to carry out R&D
- Pawgenes raises money and provides \$100K in sponsored funds to Cornell with Amanda as the PI
- Amanda's lab and staff/students have the tools and expertise;
 the money could fund a Masters student





Case 3: Smith and Pawgenes

Significant Conflict of Interest; allowed under strict management

- A Co-PI appointed for award (in addition to Conflict Manager)
- Additional oversight for use of animals
- Conflict Manager reviews budget and expenses
- Disclosure to students, staff, collaborators and publications
- Students can be involved only with permission from DGS and Special Committee; milestones established for students
- No-cost-extensions monitored
- Purchases from the company for Cornell research must be approved by Conflict Manager and disclosed to the sponsor



Case 4: Faculty student business partners



Samantha (Sam) 4th year PhD student GRA on federal funds

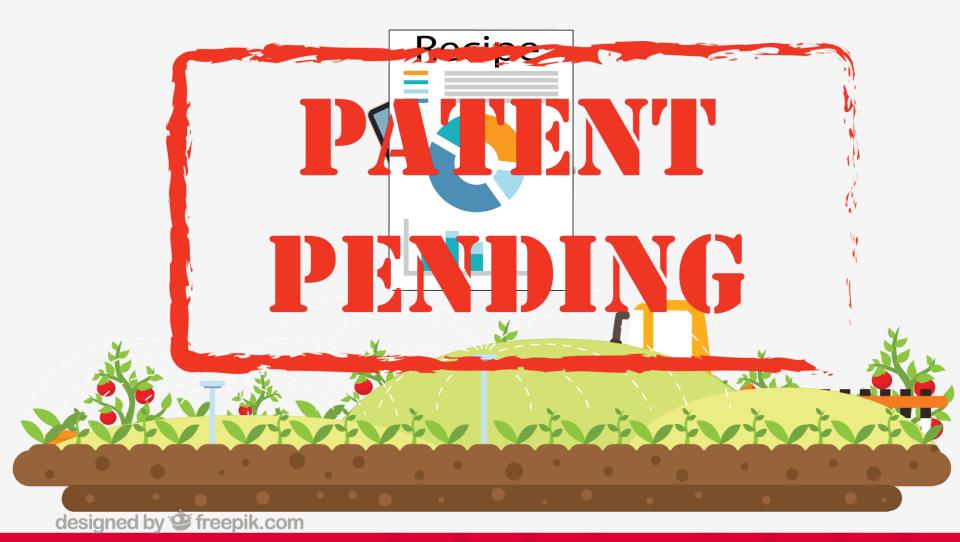


Andrew Gates, faculty
Sam's Special Committee Chair
PI on grant that funds Sam





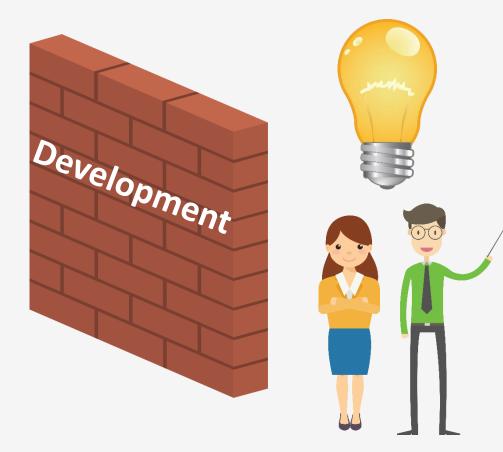
Co-invented a technology that will allow farmers to customize the amount of pesticide applied based on real time crop analysis





Potential Licensees and Investors want to see more evidence that the technology can be developed, before committing funds.





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Sam expects to schedule her B exam soon; after graduating she wants to focus on commercializing this invention



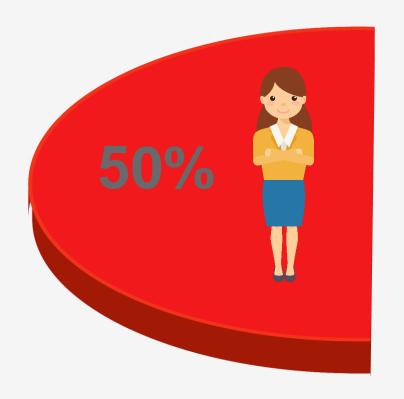


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Andrew wants to participate in the company but will continue in his faculty role.



Andrew and Sam decide to start their own company "FeedSmart" to license this tech from CTL





- Sam is eager to get started
- She wants to work on this as she is finishing up her PhD
- Andrew wants to use his "one day a week consulting allowance"



Case 4: Sam, Andrew and FeedSmart

Guiding Principle: Faculty guidance to students must be governed primarily by the academic interests of the student and not by considerations of personal financial gain.

Potential problems:

- Permitting a student or advising her/him to spend an inordinate amount of time on company activities
- Directing research toward a topic of interest to the company and not the student.
- Generally treating –or appearing to treat-the student more favorably than other students or postdocs.

Therefore: A student and her/his faculty supervisor **CANNOT** be involved in outside financial activities together while in an academic relationship (faculty advisor, current instructor, member of the special committee)



Case 4: Sam, Andrew and FeedSmart

Allowed with strict management plan:

- Sam 's B exam date must be within 3 months of signing the plan
- Company can be incorporated after Sam clears the B exam
- Sam's DGS and committee must be informed of the company
- Sam must certify that she will not spend more than 8 hours a week on company activities
- A Conflict Manager is appointed
- Andrew's students and staff are informed of the relationship and can discuss concerns with Conflict Manager
- Standard management plan terms apply to Sam and Andrew



Case 5: SBIR Award from Faculty Startup

Mary and her ex-student George co-invented a non-flammable polymer electrolyte to be used in Li batteries.







- After graduating from Cornell George and Mary started a company "PoLi-Batt" based on the technology. George is the company's CEO.
- The company submits SBIR Phase I application to DOE



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Case 5: SBIR Award from Faculty Startup

- The company has no lab or facilities of its own
- The SBIR includes a Subaward to Cornell, with Mary as the Cornell PI.
 George will work closely with Mary's students.
- The SBIR is for 6 months, \$100K in total funding; \$35K to Cornell
- The SBIR is awarded and Mary wants to start the work on the Subaward





Case 5: George, Mary and PoLi-Batt

Presents a significant conflict of interest, however...

Considerations:

- An SBIR Phase 1 award is an important early funding mechanism
- The project is a small dollar value with a short duration
- Since Mary is a co-inventor, she has the necessary expertise to oversee this project
- Federal COI rules exempt SBIR Phase I projects from regulations regarding COI



Case 5: George, Mary and PoLi-Batt

Therefore, allowed with special conditions (in addition to standard management plan)

- The sponsor is informed about the Cornell Pl's relationship with the company
- Special committees of Cornell students involved in the project are informed of the COI
- George's involvement limited to training the students and staff
- The department administrator informed
- No advance spending on the award



Overarching principles

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Guidance

Faculty should:

- Disclose their outside interests promptly and fully
- Ensure consulting relationships do not place restrictions on Cornell research or publications or claim university IP, don't involve Cornell students or staff or resources
- Prior to entering into an entrepreneurial relationship, consult the COI staff to help plan any COI management (coi@cornell.edu)

