Conflicts of Interest and Entrepreneurship

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Cornell Policies on Conflict of Interest

• Cornell Policy 1.7, Financial Conflicts of Interest Related to Research:
  – Compliance with federal and other sponsor requirements
  – Applies to Cornell academic staff and research personnel
  – Faculty Committee on COI implements the policy

• Cornell Policy 4.14, Conflicts of Interest and Commitment:
  – Managed by the Counsel’s office and the Dean of Faculty
  – Applies to all Cornell persons and functions

• Cornell Faculty Handbook
Financial Conflict of Interest (fCOI) Related to Research, defined

“A real fCOI arises when a financial interest, or other opportunity for personal financial gain, is likely to compromise or influence the objective design, conduct, reporting, or direct administration of research.

An apparent fCOI arises when there is a reasonable apprehension, which reasonably well-informed persons are likely to have, that an individual’s opportunity for personal financial gain could compromise or influence the design, conduct, reporting, or direct administration of research.” *

*http://www.dfa.cornell.edu/treasurer/policyoffice/policies/volumes/academic/financialconflict.cfm, pp6
Reason and Purpose

Ensure that there is no reasonable expectation that research results are biased by the external commitments and financial interests of persons who are responsible for university research.

Promote academic freedom with responsibility:

– assure open publication of research results
– maintain integrity of the research process
– adequate protection for students
– protect the public’s investment
– protect the institution
– maintain the public trust in the integrity of the university’s research and education mission
– encourage a spirit of entrepreneurship
Story 1: Butter

From a recent study “contrary to expectations, people who included up to 2 tbps of butter every day, were able to successfully reduce their weight and manage their weight loss over longer periods of time, regardless of age…”

Scenario 1: Findings published in the Journal of Nutrition, lead author Dr. B is a researcher at a University. Researchers have NIH funding.
Story 1: News Story

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Scenario 3: Findings published in the Journal of Nutrition. Study conducted by researchers at a University. Funding for the research provided by the Dairy Farmers Association of America.
From a recent study “contrary to expectations, people who included up to 2 tbsp of butter every day, were able to successfully reduce their weight and manage their weight loss over longer periods of time, regardless of age...”

Did the information about the researchers make any difference in your perception of the integrity of the research results?
From a recent study “…Getting a scan for lung cancer every five years reduces the probability of death from lung cancer…”

Scenario 1: Published in the Journal of Oncology. Lead author Dr. A is a prominent University researcher who works with hospitals and service providers to track interventions and outcomes. Researcher has a solid publication record, large research group, NIH funding.
Story 2: Lung cancer

From a recent study “...Getting a scan for lung cancer every five years reduces the probability of death from lung cancer...”

Scenario 2: A’s research is sponsored by a non-profit organization that is funded by some tobacco companies.
Story 2: Lung cancer

From a recent study “...Getting a scan for lung cancer every five years reduces the probability of death from lung cancer...”

Scenario 3: Dr. A’s research led to the development of innovative scanning and recording technology that was patented and licensed by a company that makes and markets the scanning equipment which was used to generate research results.

Dr. A gets royalties from the sale of the equipment and use of the licensed technology. One of the outcomes of this research result may be an increase in the number of people who get scanned.
Story 2: Lung cancer

*From a recent study “...Getting a scan for lung cancer every five years reduces the probability of death from lung cancer...”*

Scenario 4: Dr. A’s research led to the development of innovative scanning and recording technology that was patented. Dr. A started a company INNOSCAN which licensed that technology and has developed prototype scanning equipment. The results published in the journal are preliminary findings from the use of this scanning technology. INNOSCAN provided funding for this study.
Story 2: Lung cancer

From a recent study “...Getting a scan for lung cancer every five years reduces the probability of death from lung cancer...”

Did the information about the researchers influence your perception of the integrity of the research results?
Typical entrepreneurship Scenario 1...

- Faculty discloses IP generated from their research
- Starts a company to license that IP, bring it to market
- Company seeks SBIR, STTR, NYS or other funding to encourage University IP to come to market
- Company wishes to subcontract part of the work to Cornell. Faculty is the PI on this subaward
- Faculty wishes to use students, staff that work under his supervision on the project
- Work will be done in the faculty member’s lab
- Results could be published
What are the issues?

What are the conflicts?
- Can the faculty member appear biased?
- Are there issues with using the Cornell lab?
- Using Cornell students or staff?
- Purchasing of equipment or services from the company?
- Budget and expenditures?
- Research results?
1. **Disclosure** (students and post docs, collaborators, staff, publications) and to sponsor prior to issuing a subaward to the external entity.

2. **Appoint a neutral third party to monitor the management of COI**

3. Use of Cornell identity

4. Use of Cornell space

5. Procurement practices

6. Intellectual Property

7. Protection of students:
   - Students and staff under direct supervision cannot be employed by the entity in which researcher has an interest.
   - Conflict Manager must meet annually with students to discuss progress
   - Annual review of compliance with the plan, by the Conflict Manager

8. In some cases, budget review by Conflict Manager
Scenario 2

- Faculty and student or postdoc disclose IP together
- Start a company to license that IP, bring it to market, OR
- Student starts the company, faculty member takes an ownership position, OR
- Faculty member starts the company and hires the student as a company employee
Process

- Researchers must disclose, fully and in a timely manner, before they establish these relationships.
- Preliminary review by COI staff, and consultation about possible options for managing any conflicts.
- Recommendations to the Faculty COI Committee.
- Committee determines appropriate plan, communicates with researcher.
- Researcher and Conflict manager responsible for compliance.
Seek guidance and assistance

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