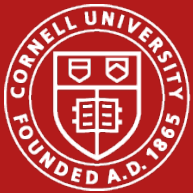


Financial Conflicts of Interest Related to Research

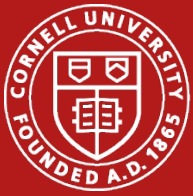
Bridget MacRae, Conflict of Interest Team Lead

<https://researchservices.cornell.edu/compliance/conflict-of-interest>



Overview

1. Conflict of Interest introduction
2. Case studies
3. Annual COI reporting cycle
 - i. New this year: expanded reporting on conflicts of commitment and foreign influence
4. Sanctions for non-compliance
5. COI processes related to proposals and awards
6. Resources



COI Regulations and Policies

Cornell Policy 1.7: Financial Conflict of Interest Related to Research

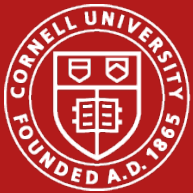
Cornell Policy 4.14: Conflicts of Interest and Commitment

Public Health Services (PHS)

- 42 CFR 50, Subpart F, Sections 50.601 to 50.607

National Science Foundation (NSF)

- 2 CFR 200; Proposal & Award Policies & Procedures Guide (NSF 19-1), Chapter IX.A



What is a Conflict of Interest?

A financial interest that is likely to compromise or influence—or *appear* to reasonably well-informed people to be likely to compromise or influence — the objective design, conduct, reporting, or direct administration of research.

Real vs. apparent conflicts

The *appearance* of a conflict of interest may be just as serious and potentially damaging as an actual lack of objectivity, and needs to be managed with equal rigor.

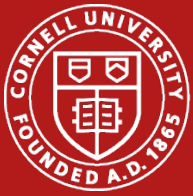


Are conflicts bad?

No: Conflicts are only a set of circumstances.

But: They can lead to real or perceived biases in the conduct of research.

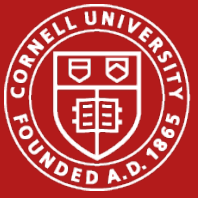
Therefore: They need to be managed effectively.



How are conflicts managed?

COI management principles require that:

- Financial interests are disclosed
- The rights of students and staff are safeguarded
- Cornell resources are not inappropriately used for the benefit of a company
- Purchases from the company are made appropriately
- An objective party oversees the conflicted research
- Periodic check-ins
- Other requirements as appropriate



Case studies

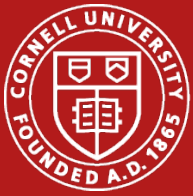
1. Faculty consulting

- with no funding from the company
- with funding from the company
- with student involvement

2. Faculty invention licensed to their company

- with no Cornell staff involvement
- with involvement of a postdoc under the faculty member's supervision

3. Direct funding from a faculty-owned company to his/her Cornell lab

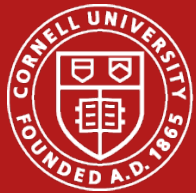


Case no. 1: Faculty Consulting

Situation no. 1: Professor Brown, an expert in food safety consults for Food Safety, Inc., but he receives no research funding or gifts from the company.

COI Determination

- No COI exists
- Disseminating knowledge through consulting efforts is a part of the academic mission, and is encouraged
- Professor Brown should be sure to separate his consulting activities from his research, ensure that no Cornell resources will be used, and confirm that appropriate separation of IP is addressed in his consulting contract



Case no. 1: Faculty Consulting

Situation no. 2: Professor Brown consults for Food Safety, Inc., and the company awards a grant to Cornell with Professor Brown as the PI.

COI Determination

- This is a COI which must be managed
- The COI is a minor one, due to Professor Brown's limited role at the company
- A simple COI management plan will be sufficient

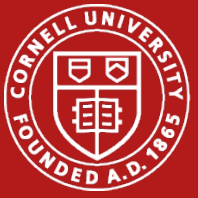


Case no. 1: Faculty Consulting

Situation no. 3: Professor Brown consults for Food Safety, Inc., which is not funding his research. Professor Brown wants his student to assist him with the consulting work.

COI Determination

- This is unallowable
- Faculty may not involve their current students in their outside activities
- Rare exceptions may be made with approval from the DGS and the student's Special Committee

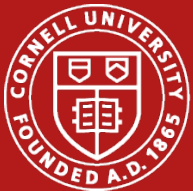


Case no. 2: Faculty IP licensed to their own company

Situation no. 1: Professor Michelle Hendee invented a software related to mining of cryptocurrencies. Professor Hendee works with Cornell's CTL to license the IP for her software to a start-up company she owns. She plans to continue to conduct related research in her Cornell lab.

COI Determination

- This is a COI which must be managed
- The COI issue is somewhat minor due to IP separation between ongoing Cornell research and the company, because no Cornell personnel are engaged in the company work, and no funding from the company is coming back to the lab
- A simple COI management plan will be sufficient

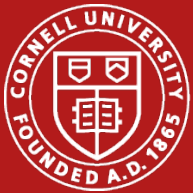


Case no. 2: Faculty IP licensed to their own company

Situation no 2: Professor Hendee and her postdoc invented a software related to mining of cryptocurrencies. They license the IP for the software to a start-up company they both own and operate.

COI Determination

- This is a COI which must be managed
- The postdoc's involvement requires that special terms apply:
 - The postdoc must reduce his/her Cornell appointment by at least 10% to account for time spent on company work.
 - The postdoc's appointment under Professor Hendee's direct supervision can continue for no more than one year after the license is assigned to the start-up.

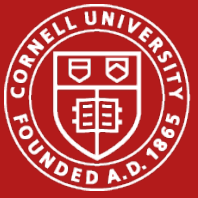


Case no. 3: Faculty member's company directly funding his research

Professor Ted Fox invented a genetic testing kit for dogs, and Cornell licensed the IP for that technology to Professor Fox's start-up company. The company doesn't have lab space to carry out some of its work, and so provides \$100K in sponsored funds to Cornell with Ted as the PI.

COI Determination

- This is a significant COI, and must be managed very carefully:
 - A co-PI must be appointed to the award
 - Budget and expenses must be reviewed by the Conflict Manager
 - Students can be involved in the research only with the permission of the DGS and Special Committee, and degree progress milestones must be set and monitored



Annual COI reporting process at Cornell

- Annual COI reporting must be completed between April 6th and May 10th at 10am
- Weekly reminder emails are sent to reporters until they have completed their reports
- College-level admins are sent weekly reporting updates for their units
- **New this year:** Some reporters will be required to provide additional information in a supplemental survey regarding engagements with foreign entities.
- Sanctions for non-compliance are effective May 10th at 10am*

** Sanctions will be implemented at a later (TBD) date for those who must complete the supplemental survey*



Who is required to report?

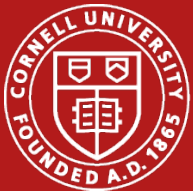
Anyone in the role of PI, co-PI, or key personnel on a sponsored proposal or award

- Including students in these roles

All academic appointees who are **not** on a proposal or award, **except**:

- Unpaid Visitors and Adjuncts
- Courtesy appointees and Emeritus faculty

Administrative staff involved in the design, conduct, or reporting of Cornell research



What must be reported?

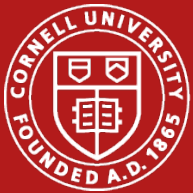
Financial relationships with organizations, private or public companies, foundations, non-profits, industry or trade groups, and international educational institutions must be reported.

Must be reported

- Consulting
- Speaking engagements
- Service on management or advisory boards
- Employment, including in your own company
- IP agreements of which you are a beneficiary
- Equity interests in private and public companies

Should not be reported

- Cornell
- US federal, state, or local government agencies
- Non-profit US institutions of higher education
- US academic teaching hospitals or research institutes
- Relationships that do not overlap with a Cornell appointment
- Volunteer or other unpaid work
- Awards from external funding agencies, executed by OSP



New: expanded reporting on foreign influence

The FBI, federal lawmakers, and sponsoring agencies have raised concerns regarding undue foreign influence on research. Expanded disclosures are required regarding engagement outside of Cornell.

- Time spent working for, consulting with, or traveling for all non-Cornell entities is required, whether it was:
 - compensated or not
 - conducted in a Cornell or personal capacity
 - performed domestically or internationally
- Disclosure of involvement in a lab or foreign talents program – whether or not any work or travel has occurred – is required
- Travel for the purposes of personal vacation or to attend a conference does not need to be reported unless paid for by a non-Cornell entity
- Some people will be contacted after May 10th, and required to provide further information in a supplemental survey



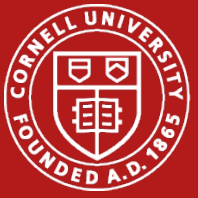
Sanctions for non-compliance

Effective on Monday, May 10th at 10 am*

Sanctions include:

- Proposals will not be submitted
- Awards will not be accepted
- Ineligibility to enter into technology transfer agreements
- Alternative PIs will be identified for existing awards
- Any salary or stipend being charged to a sponsored award will be frozen
- For PHS funded investigators, the sponsor will be notified of the non-compliance
- Visitor, Adjunct or Courtesy appointments will be terminated

**These sanctions will also apply to those who are required to provide additional information regarding foreign activities via a supplemental survey, and miss the deadline (TBD) to do so.*



Annual COI reporting and Sponsored Programs

During the annual COI reporting cycle (April 6th - May 10th at 10 am), proposals will be submitted and awards accepted based on 2020 COI reporting data

After May 10th OSP will:

- Submit proposals only if all key personnel have completed a 2021 COI report
- Distribute award funding only if management plans for any COIs related to the project, for any key personnel are in place



FCOI ORIA Contacts

Team Lead: Bridget MacRae – bm483@cornell.edu

COI Assistant: Ciara Schiess – cd566@cornell.edu

Research Compliance Associate: Judy Wood – jrm7@cornell.edu

COI Compliance Associate: Dan Alexander – dra65@cornell.edu

General COI mailbox: coi@cornell.edu

For additional information, visit the FCOI website:

<https://researchservices.cornell.edu/compliance/conflict-of-interest>