

Conflicts, startups, & you: What ethical considerations and university rules you need to keep in mind when starting a company

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Ethical considerations and COI

Most conflicts of interest can be managed by a combination of disclosure, oversight, and attention to the key principles of transparency, independence, and separation.

Transparency

- Immediate supervisors (disclose in OAR system)
- Members of the research group
- Any co-investigators participating in research involving the licensed technology
- The scientific community through disclosure of personal interests in any presentations or publications of research involving the licensed technology
- Study subjects where human subjects research is approved by the IRB and the IRB Subcommittee on COI

Separation

- SBIR/STTR, high potential for the appearance of irresolvable COI
- University employee cannot conduct research or administrative activities in conjunction with an SBIR or STTR project on behalf of both the university and the grantee or subgrantee company.
- Individual cannot serve as both the small business PI and the university subcontract PI, nor may that person contribute to both small business and university components of a single project as an employee, investigator or consultant.
- Activities conducted by the small business and by the university (personnel, budget, & resources) must be delineated.
- Inventors who continue to work with the licensing company, whether as officers, board members, consultants etc...must be vigilant that their personal work with the company is distinct from their university activities.

Independence

- Potential for appearance of improper influence:
 - Research results, purchasing decisions, assignment of resources
- Inventors can minimize appearance of bias by...
 - Recusing yourself from decisions related to the company
 - Ensure independent review where recusal is not possible
- Assigning these responsibilities to an individual who is supervised by, reports to or is otherwise subordinate to the conflicted individual does not ensure independence
 - Subordinates may still feel pressured to produce results favorable to supervisor's interests

Startups & University IP

- Startup – Newly formed company created to develop Intellectual Property
 - Compare to licensing to an existing company
- University IP – patents, copyrighted software, research tools

Conflicts of interest and commercialization

- Predictable, expected and desired result of research and commercialization efforts at the university
- Public perception of influence
- Influences
 - Results driven by seeking commercial interest
 - Revenue streams from licensing
 - Shares/ownership from licensing
 - Faculty role in technology commercialization
 - Time spent on technology commercialization

Office for Ethics in Industry Engagement

- Mission:
 - Supporting an environment of professional and research integrity
 - Assisting faculty and staff with strategies for conflict management
 - Dedicated to promoting ethical business interactions with industry

Office for Ethics in Industry Engagement

- Role:
 - We are here to protect you, your research and the university
 - Periodically review Conflict Management plans as they relate to incoming awards (SRS) or new companies; make revisions/updates where appropriate
 - Meet with students impacted by potential conflicts
 - Ensure that the relevant College and Graduate School is aware of the faculty member's company and any graduate student involvement
 - Ensure any conflict arising out of use of university facilities and services is appropriately managed when applicable (e.g., lease agreements)

Technology Accelerator for Commercialization

- Guiding Principles & Mission:
 - **To accelerate** the development of nascent inventions and technically creative works conceived by UC faculty in all applicable colleges and disciplines
 - **To maximize** the value of these promising early-stage technologies for the benefit of UC, faculty, and society through licensing UC intellectual property and supporting startup business formation
 - **To educate** UC faculty in entrepreneurial activities as it pertains to technology commercialization
 - **To connect** UC's innovation ecosystem by building internal bridges among schools and administrative departments, and engaging with external industry and investors to effect UCTAC's mission

Faculty obligations

- Primary professional allegiance to the university
 - commitment of time and intellectual energies should be to education, research, and scholarship programs of the institution
- To act with honesty, integrity, and in the best interest of the university when performing their duties
- To abide by the highest professional standards
- To disclose all outside activities
- To assign all rights in university inventions to UC

University rules, policies, guidelines on Ethics/COI

Enabling Acts	Description
University Rule 3361:10-17-03	Conduct and ethics: Code of Conduct
University Rule 3361:10-17-08	Conduct and ethics: Policy on conflicts of interest in the conduct of research at UC
University Rule 3361:10-17-09	Conduct and ethics: Employee financial interest in private companies that are commercializing university discoveries, inventions or patents
University Rule 3361:30-21-02	Employment: Policy on collateral employment for faculty members and librarians
University Rule 3361:30-21-03	Employment: Policy on collateral employment for all employees (excluding faculty and librarians)
College of Medicine – Policy for Industry Relations	College of Medicine policy and guidelines for industry relations
Conflict of Interest on Federally Sponsored Projects	Federal agencies sponsoring research require the university to maintain this policy as a condition for receiving federal grants. The requirements embodied in this policy are applicable to all proposals and subsequent awards submitted to and accepted by those federal agencies.
IRB Conflict of Interest Policy	Conflict of interest policy and statement for the UC IRB
Outside Activity	A web-based system for preparing, reviewing, and approving Outside Activity Reports of collateral employment and conflict of interest

University rules on Intellectual Property

Enabling Acts	Description
University Rule 3361:10-19-01	Patents and copyrights: policy on inventions and discoveries.
University Rule 3361:10-19-02	Patents and copyrights: copyright policy.

Faculty Roles in a startup

- Examples:
 - CEO
 - Principal scientist
 - Consultant

Industry Interactions with the University

- Licensing technology
- Sponsoring research
- Purchasing services
- Leasing space
- Consulting

Considerations for Conflicts in Industry Interactions

- Things that need to be considered:
 - Outside Activity
 - Collateral Employment
 - Conflict of commitment
 - Conflict of interest in Commercialization
 - Conflict of interest in research
- General Solution – Conflict Management Plan (CMP)

Conflict of Commitment

- “*Collateral Employment or Outside Activities*” means any effort (to include employment or service), whether within the university or with an external entity, including consulting work, that is in addition to an employee’s existing “UC” employment responsibilities (Board Rules 30-21-02 and 30-21-03).
- Usually involves issues of time allocation
- Outside activities exceed the permitted limits per employment contract and/or Chair/Dean’s expectations, or whenever a full-time faculty member’s primary professional loyalty is not to UC.

Conflict of Interest

- Conflict of interest: Circumstances that create a risk that professional judgments or actions regarding a primary interest will be unduly influenced by a secondary interest
 - Primary: welfare of patients/participants, integrity of research, quality medical education
 - Secondary: pursuit of professional advancement, financial interests, favors for family
- COI: *potential* to threaten the integrity of the researcher, the University, academic research, training and other activities

Board rule 10-17-08

Policy on conflicts of interest in the conduct of research at the university

- Disclosure in OAR (reporting outside activity, 30-21-01)
- Training
- COI Committee: 7 members
 - President appoints 2 CoM, 2 CEAS
 - Faculty senate elects 3
- Conflict management plan (CMP) is reviewed, approved by VPR

Board rule 10-17-09

- Permits faculty, staff, students who create new technology the ability to hold personal financial interests in companies that are engaged in commercializing the invention
- Provides exception to Ohio Ethics laws prohibiting public officials from having an interest in the profits or benefits of a public contract entered into by or for the use of the governmental unit (UC) with which the employee is connected
- Approval requires:
 - 1. Compliance with collateral employment requirements (OAR disclosure)
 - 2. Conflict management plan (CMP)

University policy: COI on externally funded projects (1.3.2, rev. 12/1/13)

- Purpose
 - Assure objectivity and integrity of the researcher, the university, and academic research, training, or other activities are not compromised or perceived to be compromised by matters of financial benefit or personal gain
- Disclosure
- [COI Committee](#)
- COI Committee determinations
- PHS-funded research and DHHS requirements (42 CFR Part 50)

Conflict Management Plan

- Draft – we have templates
- Submit – send to Holly
- Review and Feedback – Conflict of Interest Committee
- Approved – VP for Research
- Timing – before we finalize a license with your startup

Conflict Management Plan Template

- Covers:
 - Background, University duties (potential COC will be managed)
 - Role in Company
 - Limitation of Equity Ownership
 - UC Research
 - Interaction with students and other personnel
 - Use of university facilities and services (university leasing)
 - Purchases
 - Publications and presentations
 - Disclosure
 - Management of financial interest

COI Committee Safeguards

- Review and analysis of research data by unconflicted statistician or co-investigator
- Collaborative study design
- Designation of an unconflicted investigator to oversee data collection
- Study blinding
- Collaborative publication
- Peer review of manuscripts prior to publication and/or grants
- Recusal from purchasing decisions or selection committees where the company is a prospective vendor

Graduate Student involvement in faculty member company

- Generally, students and other trainees *are not* permitted to participate in activities where the supervising faculty member has a conflict of interest with the sponsor (see 10-17-09)
- Exceptions may be made with the approval of the COI Committee, the VPR and others involved as determined in the CMP
- Where exceptions are made, students must be fully informed of the conflicting relationships, have the opportunity to decline to participate, and have an alternative project available
- Training experience and academic progress of university students must not be subordinated to personal financial interests of inventors or commercial interests of research sponsors

Case example: Eccrine Systems, Inc.

- Faculty member: Jason Heikenfeld, PhD (EECS/CEAS) [and Associate Vice President of Technology Accelerator for Commercialization]
- Effective December 2014
- Eccrine: Developing non-invasive, electronic wearable systems that measure and transmit real-time data about human sweat
- Company role: Chief Science Officer
- Initial equity ownership: 50%, now below 25%
- University role: 50% faculty, 50% staff
- Research funding: NSF, AFRL, ODHE/OFRN
- Graduate students: 4 PhD students and 1 MS student
- Full disclosure in OAR including CMP attached

Eccrine – UC interactions

- AFRL funds two projects to Eccrine, Eccrine subcontracts to UC
 - PI at Eccrine: Dr. Gavi Begtrup
 - PI at UC: Dr. Jason Heikenfeld
 - No restrictions on publishing or patents
- Jason's current role in the company has already been reduced to Chief Science Officer, involved 2-4 hrs per week; equity ownership diluted to under 15%
- Eccrine rents space in Jason's lab (pilot project)

Management of the conflicts

- Jason is removed from:
 - All final decisions related to his inventions or technology related to sweat biosensing technology
 - How to proceed with other inventions or technology at UC that could be competitive with his research and/or with Eccrine
 - Any negotiation of licenses to IP or other agreements between UC and Eccrine
- Jason discloses his role and ownership to:
 - All non-Eccrine collaborators on projects; no collaborators are associated with Eccrine
 - All applicable presentations and publications

Students

- Several students Jason mentors are working on projects in the field of sweat sensors funded by AFRL, NSF, OFRN. Research activities are solely in support of directions/priorities provided by the funder, not Eccrine.
- Jason continues to be chair of dissertation
- Protections:
 - One or two independent (unconflicted) professors are assigned to each graduate student to periodically review the student's academic and research progress
 - Both the student and professor sign agreements which outline expectations for providing said oversight and ensuring the integrity of the research (minimizing any potential influence or pressure from Jason)
 - Student is aware of mentor's company and his ownership interests
 - Student is reminded of individuals to contact should concerns impropriety arise

Take Homes

- We are here to protect you and the university
- Make yourself familiar with the rules and the contents of a conflict management plan early
- Have the discussion with your leadership, both UC and company early with regard to your role and its impacts

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Feedback

<https://www.surveymonkey.com/r/ResEthics>

