

UMass Amherst Policy on Conflicts of Interest Relating to Intellectual Property and Commercial Ventures

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UMass Amherst Policy on Conflicts of Interest

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History of Conflicts Policy

- Prior to 1996, UMASS employees were subject to state ethics law (268A) and the oversight of the state ethics commission for all COI matters, including commercialization of University technology
- This severely restricted the University's and faculty's ability to engage in University-industry relationships (e.g., sponsored research, start-up companies, tech licensing) with companies in which faculty had a financial interest
- As permitted by the five-campus merger legislation, a system-wide task force developed proposals for a first-ever policy and procedures for governing COI in matters related to tech commercialization
- The policy was approved by the Board of Trustees in 1996, subject to collective bargaining with the campuses (except Worcester)



UMass COI Policy Philosophy

- UMass assumes faculty and staff act with highest levels of responsibility, integrity, and commitment.
- UMass is supportive of licensing, industry partnerships, start-up companies, and the like.
- However, engagement with private companies has the potential for inappropriately diverting the University from its core mission.
- Such engagements need to be disclosed, reviewed and managed carefully.



Record to Date

- The COI Committee and the campuses have evolved considerably over time in their ability to anticipate and manage COI situations
- The COI Committee has successfully handled over 130 cases since 1996
- Only one faculty member has refused to comply with a COI ruling and left the University



EXAMPLE #1

- Facts: A faculty has a substantial financial interest (e.g., equity, consulting) in a company which is doing clinical trials of a promising new device at UMass and is asked to lend their special expertise to the project
- Concern: The potential for bias in the design or conduct of the trial by the conflicted faculty member who would personally benefit from positive results
- Managed: Ban the faculty from participating in the clinical trial



EXAMPLE #2

- Facts: Faculty has a very modest amount of stock and consulting arrangement in a small company and seeks to take on a small sponsored R&D agreement from that company to their lab
- Concern: The potential for impacting the integrity of University research
- Managed: Require public disclosure of the financial interest in public presentations...establish campus oversight committee with regular reporting requirements



EXAMPLE #3

- Situation: A faculty has a significant equity and consulting arrangement in a start-up company developed around UMass technology. There is a desire to play a leadership role in the company, consult extensively, secure sponsored R&D, hire students to work at the company, etc.
- Concern: Potential for impacting integrity of University research, the educational experience of students, the ownership of IP
- Managed: Establish campus oversight committee to monitor case...prohibit the faculty from taking on an officer position or board seat...instead allow participation on SAB...consider another PI or co-PI for sponsored R&D...require disclosure of financial interests in public presentations...ensure faculty has no academic oversight of students working at their company...carefully delineate roles at UMASS vs. roles at company to protect IP...etc.



Purpose of COI Policy

- Overcome limitations of state ethics law
- Encourage/facilitate appropriate
 relationships between faculty and industry
- Protect research integrity, educational mission, reputation of University
- Complement to IP Policy
- Link: http://www.umass.edu/research/ora/confl/html*

^{*}link removed because document no longer valid.



State Ethics Law

- You may <u>not</u> take any official action which might affect your financial interests or those of your family.
- You may <u>not</u> have a financial interest in a contract between the University and an outside entity.
- You may <u>not</u> use your official position to obtain privileges or special treatment.
- You may <u>not</u>, after leaving public service, take a job involving university contracts with which you participated as a university employee.



Scope of COI Policy

- Conflict between personal interests of faculty member, student or staff, etc. and the interests of the University or the perception of a conflict
- Any interest of immediate family members
- Includes any use of students, outcome of research, or technology transfer with significant use of University funds, facilities or equipment



Multiple Conflicts Disclosures

- Federal Conflicts Disclosure
- University Conflicts Disclosure
- Journal/Conference Disclosure Requirements
- Consulting & Outside Activities Policy
 - □ No use of students or facilities
 - Disclosure to Department Head
 - Outside Activities Policy Does Not Apply to Conflicts



Links to Forms & FAQs

NIH Federal Conflicts Policy FAQs

http://grants.nih.gov/grants/policy/coifaq.htm#c13

OGCA Federal Conflicts Form

http://www.umass.edu/research/ogca/policies/conflict.htm*

OGCA University COI Form

http://amherst.cvip-umass.net/_users/pdfs/conflict.pdf*

^{*}links removed because documents are no longer valid.



UMass COI Policy Case-by-Case Evaluation

- Disclosure to Vice Chancellor for Research of new (& changes to prior disclosed)
 Conflicts of Interest
- Referral to Committee Chair and Counsel



Committee Review

 All Conflicts Involving Substantial Financial Interest Come Before Conflicts Committee Meeting

 Conflicts Involving Significant Financial Interest Ordinarily Allowed Without Meeting



Significant Financial Interest:

- ordinarily allowed after disclosure
- >1% Equity or equity valued > \$10,000
- >\$10,000 received or contracted

Federal Rule

- >5% Equity or equity valued > \$10,000
- >\$10,000 received or contracted

Substantial Financial Interest: goes to COI Meeting

- >5% Equity (or equity valued > \$100,000)
- >\$100,000 received or contracted (and a clinical trial involving ANY equity or other value in excess of \$1,000)



Division of Labor

- System-wide Conflicts Committee
 - 1 faculty member and head of research from each campus
 - □ President or designee
 - □ 2 non-voting members
- Conflicts Committee faculty peers and research leaders willing to meet monthly to aid University to meet its COI obligations
- Campus Oversight and Management is primary vehicle for ensuring compliance



Committee Meetings

- Amherst Members
 - Dr. Paul Kostecki, Vice Chancellor for Research
 - □ Dr. Ethan Katsh, Dept. of Legal Studies
- Disclosures are Confidential
- Monthly Meetings



Financial Interests

Equity (stock, options)

- Non-equity (salary, gifts royalties, consulting fees, honoraria, goods, services, travel expenses)
- Federal Rule/Journal Rules: Patents& License Revenue under IP Policy

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UMass COI Policy Disposition

- Postpone (lack sufficient info. to review case)
- Approve (deliberation reveals no conflict)
- Approve with conditions, such as:
 - □ Public disclosure of conflict in publications
 - □ Comply with Federal Agency Disclosure Requirements
 - □ Monitoring/ Reporting to Campus
 - □ IP from Consulting Activity Subject to Ownership by University Under Standard IP Rider attached to Consulting Agreement
 - □ Sale of Equity and Caps on Future Equity Interests
 - □ Prohibition of Student Involvement / Change Thesis Advisor
 - □ Resignation of Board/Officer Positions
 - □ Co-PI for Research
- Deny (if PI refuses conditions established by Committee)



Appeals Process

- Rehearing (at next regularly scheduled meeting)
- Review by Ad Hoc Faculty Committee
- President (whose decision is final)

Public Statements

Conflicted Person is Prohibited from Making Public Statements before Publication in Journal or Scholarly Meeting when Conflict Involves Conduct of Research for Company



Some Conflicts Guidelines

- With proper disclosure and campus oversight, you may form a start-up to license UMass IP
- Under the proper circumstances, you may serve as an employee or stockholder in a UMass licensee
- If you own more than 5% of a well-capitalized company, you cannot serve as PI for your company on a UMass SRA



SBIRs/STTRs

SBIR

- Co. must perform at least 67% of effort in Phase I and at least 50% in Phase II
- UMass can perform balance of work
- Co. PI must be employed at least 50% time by co.

STTR

- UMass must perform at least 30% of effort
- Start-up must perform at least 40%
- Co. PI level of employment not stipulated



SBIR/STTR Conflict

- Facts: UMass PI is part owner & President of STTR recipient co. (formerly disclosed to Dept Head under Outside Activities Policy), wishes to be UMass PI and Co. PI on award, and for his student to be on UMass side of work
- Concern: Manipulation of work, student coercion
- Managed: Another PI must be Co. PI, appoint another PI as thesis advisor or co-advisor, delineate project tasks to protect UMass IP...etc.



UMass COI Policy Assistance

- Campus
 - □ Campus COI Policy
 - □ "Guidance Principles"
 - □ Department Chair/Dean
 - □ Vice Chancellor for Research
 - □ Oversight Committee for Your Case
 - □ Campus COI Committee Member
- System
 - □ Counsel to COI Committee
 - COI Committee Chair