

HARVARD UNIVERSITY POLICY ON INDIVIDUAL FINANCIAL CONFLICTS OF INTEREST: Frequently Asked Questions

(Last Updated May 4, 2012)

While the following list of frequently-asked questions is by no means exhaustive, and is not a substitute for the policies to which it refers, it is designed to highlight scenarios under which Harvard faculty members commonly encounter financial conflicts of interest (fCOIs), explain briefly the rationale behind applicable University-wide and School-specific policies, explain how and when to disclose financial interests, and direct interested faculty members to the policies that best address their particular fCOI concerns.

Some provisions of the University-wide fCOI Policy and related School-specific fCOI policies overlap, or arise out of, more general policies of the University. Where appropriate, those broader policies also are mentioned below.

If your question is not answered below, please send an email to fcoihelp@harvard.edu, or contact your school's Designated Institutional Official.

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1. What is the Harvard University conflict of interest policy?

On May 26, 2010, the President and Fellows of Harvard College approved a University-wide policy on Individual Financial Conflicts of Interest. This policy provides guidance for school deans, faculty and other individuals holding teaching appointments, in identifying, evaluating, and managing conflicts of interest. The policy requires annual disclosure of financial interests related to an individual's University activities. A faculty member's disclosures are reviewed and conflicting interests are managed by his or her own School.

The University policy anticipated many of the changes to federal regulation published by the US Department of Health and Human Services (HHS) in its Final Rule on the *Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors*. The Rule, released on August 24, 2011, implements significant changes to regulations last updated in 1995 that govern the relationships between PHS-funded investigators and industry.

The University policy delegates to individual Schools the authority to determine the details of the information that faculty must disclose. You should familiarize yourself with your School's policy; in some instances School's may require the disclosure of more information than is required by the University policy.

2. What is a conflict of interest?

An individual financial conflict of interest is a set of circumstances that reasonable observers would believe creates an undue risk that an individual's judgment or actions regarding a primary interest of the University will be inappropriately influenced by a secondary financial interest.

To recognize the existence of a financial conflict of interest is not to pass judgment on the character or actions of an individual and does not per se imply wrongdoing.

3. How do I know if I have a conflict of interest?

The University Policy on Individual Financial Conflicts of Interest requires that you disclose to your School all *significant financial interests in related outside entities*. Your School will then review your disclosed interests and, in consultation with you, will determine whether any of them represents a conflict.

4. What do I need to disclose to Harvard?

What you need to disclose is determined by your School's policy. At a minimum, you must disclose all *significant financial interests in related outside entities* – both your own and those of your spouse and dependent children. You need only disclose interests in **related outside entities**. When in doubt, disclose.

You must disclose:

- (1) financial compensation, including travel, from consulting, employment, managerial, and fiduciary relationships that, when aggregated over the preceding twelve months, exceed \$5,000;
- (2) equity and other financial interests above \$5,000;

- (3) equity interests of any amount, or entitlement to the same, in a non-publicly traded, for-profit, entity; and
- (4) intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income related to such rights and interests.

But, *only* when such interests are in an entity in which your significant financial interest may, or may reasonably appear to an outside observer, to influence the discharge of teaching, research, or other University-related responsibilities. This includes entities:

- (1) whose products, services or activities are related to the areas of your teaching or research;
- (2) that fund research in your area of academic interest;
- (3) that own or have rights to develop intellectual property that is the subject of research in which you participate;
- (4) that compete commercially with such an entity as described in (3);
- (5) that make or propose to make a gift to the University that would support your teaching or research activities;
- (6) that furnish products or services to the University through a contractual process in which you participate in any way;
- (7) that propose to enter a licensing agreement with the University with respect to technology invented by you;
- (8) that act as a legal or *de facto* agent for any outside entity engaged in any of the above activities.

Travel

Additionally, beginning August 25, 2012, any investigator receiving funding from the U.S. Public Health Service (PHS) must disclose the occurrence of any reimbursed or sponsored travel (i.e. that which is paid on behalf of the investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

5. Must I disclose mutual fund holdings?

No. You are not required to disclose financial interests of any amount in diversified financial holdings. When determining whether to report equity (stocks, stock options etc.) consider whether you actively control your investment in the equity holding (if the holding is in a mutual fund or blind trust, you do not, whereas if you were given stock options in a start-up company in lieu of other payment, or if you purchased or inherited stock in a company, for example, you do.) When in doubt, disclose.

6. What if don't know the value of my equity holdings?

If you believe the value of your equity to be more than \$5,000 (or above \$0 in the case of privately-held, for-profit entities) and the equity is in a **related outside entity**, disclose. The online disclosure form does not require that you disclose exact dollar amounts of significant financial interests.

7. Must I disclose royalties?

Maybe. You are not required to disclose royalties or other remuneration paid through Harvard. You must disclose royalties from related outside entities, and *not paid through Harvard*, that when aggregated over the past twelve months exceed \$5,000. These include royalties that derive from the publication of textbooks or other scholarly works, *if your income from these royalties exceeded \$5,000 in the last twelve months*. By requiring that you disclose income from royalties, the University does not intend to restrict your receipt of such royalties. Disclosure of royalty income allows your school's designated institutional official to determine whether such income constitutes a conflict of interest and if so, whether the conflict should be managed. Appropriate management *if a conflict is determined to exist* protects both you and the University from allegations of bias in teaching and research.

8. When do I need to disclose to Harvard?

You must disclose your significant financial interests at least annually and as determined by your School's Implementation Plan. You must also update disclosed information (e.g. a change in value of a previously reported interest) at least annually; within 30 days of the discovery or acquisition of a new financial interest; and prior to accepting gifts, submitting an application for a sponsored project, or initiating a technology licensing agreement.

Investigators currently receiving or planning to apply for funding from the US Public Health Service must disclose the occurrence of sponsored or reimbursed travel (see: *What do I need to disclose?*) within 30 days of the date of travel.

9. I have appointments in more than one School – do I have to disclose twice?

Maybe. In general, you should disclose through the School with which you have a primary appointment. If you have equally-weighted appointments in more than one School you should consult with the Designated Institutional Officials or your department administrator to find out to which School to report. In some instances, faculty may be required to file two disclosures.

10. Who will have access to the information I disclose?

Every School electing to use the University online disclosure platform designates one or more individuals to receive and review uploaded financial interest disclosures. Upon notification from the Dean of a participating School, HUIT establishes permissions for designated individuals to access disclosures of faculty members and others who disclose to their School. No other person, inside the School or outside it, may access information provided by users. Every School establishes its own policy specifying who will have access to disclosures in order to review them.

HUIT employees, under strict confidentiality requirements, may have access to personally identifiable information for authorized system maintenance purposes.

11. How will the information I disclose be used?

The information you disclose will be used *only* to determine if you have a financial conflict of interest with your University responsibilities that may require management under the University or research sponsor's conflict of interest policies.

Disclosures are held in confidence, and released only to those institutional officials and bodies with a need to know, as authorized by each School's Implementation Plan.¹ Disclosed information, either as it pertains to an individual or in aggregate, will be used (a) to assure compliance with conflict of interest policies and regulations; (b) to comply with subpoenas and other legal obligations; and/or (c) as stipulated in a school's implementation plan.²

Preserving the privacy of disclosures made under school policies is essential, and failure by any member of the Harvard community to honor the privacy of disclosures will be regarded as a violation of his or her duties to the University, and may be the basis for disciplinary action.

12. Will my department chair, Dean, or other official see the information I disclose?

Each School's implementation plan describes the review process for disclosed financial interests. You should consult your School's Implementation Plan to determine the process of review and who will be a part of that process.

13. Is the information I submit secure?

Yes. The annual disclosure system was written in Java and runs on Tomcat, backed by an Oracle database. It is housed on a server maintained by Harvard University Information Technology (HUIT) and is in compliance with the [Harvard Enterprise Security Policy](#). The responses provided in the online forms are the only user information that is gathered, and data passed between the browser and the server is encrypted using SSL.

¹ There may be circumstances in which the University, in order to comply with judicial subpoenas or government agency demands, may be compelled to make an external disclosure of information relating to conflicts of interest; in such cases, in order to prepare responses to such demands, limited disclosure to the Office of General Counsel and University administration may also be required.

² In their implementation plans for the University policy, schools may choose – but are not required -- to address conflicts of commitment; in those cases, implementation plans should make clear that disclosures of significant financial interests and fiduciary roles may also be used for analysis of potential conflicts of commitment.

14. As a Harvard faculty member, I sometimes am asked to participate in outside activities for which I am offered financial benefits (e.g., consulting fees, honoraria, equity in companies). Am I permitted to accept such benefits?

In general, yes. Your receipt of such benefits, however, may raise a “financial conflict of interest” (or, “fCOI”) that must be managed according to University-wide and School-specific policies, so as not to compromise either your primary obligations to the University, e.g., with respect to your Harvard research and teaching, or the University’s public mission and reputation. If the entity with which you are engaging in outside activities is a *related* entity, and your financial interest exceeded \$5,000 in the last twelve months, you must internally disclose the interest to your School.

The University-wide fCOI Policy, School-specific fCOI policies and others³ govern how to manage your research, teaching and other University duties when you receive financial benefits from outside sources.

15. Instead of me, what if a member of my family receives the financial benefit?

The financial interests of your spouse and any dependent children may be treated as if they were your own for purposes of fCOI disclosure and management.

16. I have been consulting for a company for many years. Recently, they offered to sponsor research in my Harvard laboratory. Would this be permitted?

Under ordinary circumstances, the University’s concerns with respect to industry-sponsored research are several-fold, and include ensuring that research conducted in Harvard laboratories is free from bias,⁴ that the academic welfare of students and other trainees is paramount⁵ and that human research subjects are protected from any undue risk of harm.⁶ These concerns are elevated when a faculty member’s relationship with a potential corporate sponsor results in an fCOI. In the case of research involving human subjects, for example, an arrangement such as you have described generally would not be permitted. Pursuant to Operating Principle 7 of the University-wide policy, a faculty member may be required to disclose such information to their school Dean prior to commencement of the sponsorship. Approval to proceed with such a sponsorship is within the discretion of the School Dean, who may withhold or condition such approval based upon considerations to reduce, manage, or eliminate any potential fCOI. Management of the conflict might include a plan to provide an independent departmental mentor for students and trainees working on the sponsored project.

³ See, e.g., the “Statement on Outside Activities of Holders of Academic Appointments” (as voted by the President and Fellows of Harvard College, effective July 1, 2000); “Principles Governing Commercial Activities of Harvard University, with application to Partnerships between the University and Outside Organizations” (as approved by the Corporation on September 17, 2001); “Policies Relating to Research and other Professional Activities Within and Outside the University” (as voted by the President and Fellows of Harvard College on March 1, 1982, amended on July 25, 1987, amended by votes of the FAS on October 29, 1987 and May 2, 1995, and amended by vote of the Faculty Council on November 15, 2000).

⁴ “Principles Governing Commercial Activities of Harvard University, with application to Partnerships between the University and Outside Organizations”, see especially Section 2 (“Freedom of Inquiry), paragraph (a); and Section 5 (“Public Trust”), preamble and paragraph (a).

⁵ *Ibid.*, Section 2, generally, and Section 4 (“Educational Welfare of Students”), preamble.

⁶ See, e.g., the “Statement of Policies and Procedures Governing the Use of Human Subjects in Research at Harvard University” (as voted by the President and Fellows of Harvard College, September 22, 2003), and the “HMS Faculty Policy on Conflicts of Interest and Commitment”.

17. I understand that companies that sponsor University research usually receive benefits in return (for example, rights in intellectual property), but a company in which I have a financial stake wishes to make a gift to my lab or department. With no strings attached, would there be an fCOI?

While some risks are lower than they might be if a company received express benefits in exchange for financial support, feelings of goodwill still can influence the recipient of a gift to extend favorable treatment to the donor. For example, knowledge of the source of funds could influence lab or department resource allocation decisions. For this reason, gifts do raise fCOI issues and are subject to disclosure and management under the Harvard fCOI Policy and applicable School-specific policies, which you should consult for further details.

18. What if a company in which I have an ownership or other financial interest wants to license an invention that I have made at Harvard?

Under the Harvard FCOI Policy and its School-specific counterparts, you are required to disclose certain of your financial interests to the University at least annually. If you learn that the University's Office of Technology Development ("OTD") may license one of your inventions to a company in which you hold such an interest, you also should disclose the relevant fCOI to the OTD staff member with whom you work, so that they may ensure that any license granted to the company complies with the University's "Policy Statement Regarding Application of Harvard University's Conflict of Interest Policies to the Granting of Licenses."⁷

19. A company in which I have a financial interest owns a technology on which I would like to perform research in my Harvard laboratory. Are there any fCOI issues of which I should be aware?

Your research on the company's technology could result in improvements that might benefit the company (and, consequently, you) financially. As such, the proposed research would be subject to disclosure and, potentially, management under the Harvard fCOI Policy and applicable School-specific policies, as may be deemed advisable in light of the facts.

20. A company in which I have an ownership or other financial interest is conducting R&D in a field in which members of my Harvard research group have expertise. If certain experiments were performed in my Harvard laboratory, the results could help the company to develop its products and make strategic decisions. Assuming that the company has not been promised any rights in my group's research results, can I conduct these experiments at Harvard? If so, can I assign students or other trainees (e.g., postdoctoral fellows) to work on them?

To the extent that you might benefit financially from a company's success based on experiments performed in your Harvard laboratory, you should refer to the University-wide fCOI Policy and School-specific fCOI policy, as well as the terms of outside funding agreements, e.g., with the U.S. government. This is true even in the absence of a formal research sponsorship or collaboration agreement between Harvard and the company. Assigning students or other trainees to such work

⁷ Approved by the University Committee on Patents and Copyrights on March 19, 1993 and by the President and Fellows of Harvard College on September 20, 1993. Revisions approved by the University Committee on Patents and Copyrights, acting under prior consent of the President and Fellows of Harvard College, at its April 22, 1995, February 16, 1996, and March 16, 2001 meetings. Amended by authority of the President and Fellows of Harvard College, as granted February 4, 2008.

may require prior approval of your School Dean. Additionally, you may be required to disclose your financial interest in the company not only to the University, but also to students and other trainees who may participate in the research, scholarly journals to which you may submit results for publication and federal agencies sponsoring your work. As under other fCOI scenarios, the School in which you hold your Harvard faculty appointment may implement oversight or management measures, especially as regards the protection of students.

21. I understand that the educational welfare of students is a key concern; however, what about Harvard staff members? Could I have them work on research that might benefit me financially?

The arrangement that you've described poses its own set of fCOI concerns; this time, around the diversion of University resources for personal business use, abuse of the supervisory relationship with staff members and breach of the public trust, and so is not permitted. For more information, please consult the Harvard fCOI Policy.

22. Instead of having them work in my Harvard laboratory on projects that might benefit a company in which I have a financial interest, could I hire my students or other trainees to perform the work?

The University recognizes that its students may wish to avail themselves of beneficial career development opportunities while at Harvard, but balances that recognition against potential detrimental effects on students from any unwanted solicitation or pressure to participate in the commercial activities of their Harvard faculty mentors. You should refer to the Harvard fCOI Policy.

23. I supervise and/or must evaluate a faculty member who participates in work in which I have a financial interest. It just feels wrong. Where can I find guidance?

Depending on your position within the University, you should consult one or both of the Harvard fCOI Policy and the "Harvard University Policy on Conflicts of Interest and Commitment for Senior Officers and Administrators".

24. I hold an ownership interest in a company that would benefit from my Harvard research, especially if I did not publish the results. May I do this?

Harvard's mission is premised upon the creation and dissemination of new knowledge through its research and teaching. Based on its capacity to benefit the public through such mission-directed activities, the University enjoys privileges and benefits not available to for-profit organizations. On this foundation of open inquiry rests the University's reputation and its continued ability to foster research and scholarship at the highest levels, as well as the public's trust. As such, Harvard's policies favor publication of research.

25. A company that wishes to sponsor research in my laboratory has asked for exclusive access to the results of the research, *i.e.*, to suppress my group's publication of the results. They even want to own the research data and any resulting inventions! What are my rights and obligations in this situation, and who can help me?

Potential corporate sponsors frequently request such restrictions to help them maintain an advantage over competitors who lack access to the results or to suppress data that could have a

negative impact on the company's business, *e.g.*, with respect to new drug approvals. A combination of University policies⁸, tax laws and federal grant guidelines are designed to protect you, your students and the public from this sort of arrangement. Fortunately, you do not need to worry: when negotiating your research sponsorship agreement with the company, OTD staff will decline to accept such terms and conditions, and instead will negotiate more reasonable terms on your and the University's behalf, in compliance with all applicable laws and policies.

26. In my Harvard teaching, as well as in publications and formal presentations, I sometimes cover research that is supported by a commercial entity or that is of interest to a company in which I have a financial interest. This material has scientific merit, and is within my recognized field of expertise. Are there any fCOI issues of which I need to be aware?

There are various fCOI issues around the situation that you have described: some are related to potential bias, others to any actual or perceived endorsement, by you or Harvard, of a company or its technology, products or services. To learn more, you should refer to the University-wide fCOI Policy, any applicable School-specific COI policies, the "Statement on Outside Activities of Holders of Academic Appointments, and the "Policy on the use of Harvard Names and Insignias". You should also comply with any journal or professional association disclosure requirements.

27. Other than in my research and teaching, how might I encounter fCOI issues that are subject to Harvard policies?

A few examples of situations in which you should consult one or more of the University-wide fCOI Policy, "Statement on Outside Activities of Holders of Academic Appointments" and (possibly) "Harvard University Policy on Conflicts of Interest and Commitment for Senior Officers and Administrators" are:

A company with which you have an ownership or other financial interest:

- Seeks confidential or sensitive University information from you; or
- Furnishes products or services to the University through a contractual process in which you participate in some way;

- You are invited to serve in a fiduciary or managerial role for an outside organization; or
- You are asked to provide expert advice in a governmental or public policy forum concerning subject matter in which you have a financial interest.
- You are offered a research gift or grant from an entity in which a family member has a financial interest.

⁸ See, *e.g.*, "Principles Governing Commercial Activities of Harvard University, with application to Partnerships between the University and Outside Organizations", Section 3 ("Openness of Inquiry"), and the University's "Statement of Policy in Regard to Intellectual Property".