HARVARD UNIVERSITY POLICY ON INDIVIDUAL FINANCIAL CONFLICTS OF INTEREST FOR PERSONS HOLDING FACULTY AND TEACHING APPOINTMENTS

As approved by the President and Fellows of Harvard College on May 26, 2010 and incorporating amendments as approved by the Presidents and Fellows on May 23, 2012.

A. INTRODUCTION

As a center of discovery and learning, Harvard University plays a prominent role in disseminating ideas and knowledge to audiences within and beyond the University. Harvard faculty members do so in part through traditional academic pursuits, such as teaching, public lectures, scholarly publications, the training of graduate students and fellows, and public service appointments. In addition, and increasingly, faculty engage in extramural interactions with industry and other external constituencies. Consultancies, advisory engagements, service on for-profit and not-for-profit boards, translational ventures, and numerous other outside activities provide opportunities for faculty to direct their expertise and learning to socially useful applications.

Faculty members' collaboration with outside organizations and communities furthers Harvard's mission of societal service and also benefits the University. Such interactions promote intellectual exchange, enhance professional development, spawn further discovery, and augment and renew the vitality of the University. Accordingly, Harvard encourages its faculty to engage with the world through outside pursuits. At the same time, the University is cognizant that an individual's relationships with outside enterprises can engender opportunities for personal gain or financial advantage that may be at odds with the primary obligations the individual assumes as a member of the Harvard faculty.

Harvard enjoys the trust of many constituencies – students and trainees, faculty members, alumni, governments, businesses, a global community of scholars, and the general public. At root, their trust rests upon Harvard's reputation for objective and independent scholarship. Indeed, the University's greatest asset is its reputation for scholarly integrity, a reputation that benefits all members of the Harvard community and undergirds the institution's merit for support in all forms – enrollments, public and private grants, donations, academic collaborations, and others.

It is therefore appropriate that the University ensure that members of its community do not engage in behaviors that risk compromising the University's reputation and integrity. Because financial conflicts of interest especially may corrode the University's reputation and, thereby, erode confidence in the University and diminish its trustworthiness and stature, the University must ensure that faculty are made aware of such conflicts and are dutiful in internally disclosing them, that disclosed conflicts receive scrupulous attention and management, and that all of Harvard's units are held to standards of conduct that meet the needs of the University as a whole.

The policy put forth here establishes a University-wide system for identifying, evaluating, and managing financial conflicts of interest. The goal of this policy is to achieve consistency across the Faculties in identifying and responding to financial conflicts of interest by providing sufficient clarity and specificity to guide University-wide implementation. At the same time, this policy is mindful of disparities among the schools in terms of the culture and nature of faculty interactions with external entities, including commercial, not-for-profit, and governmental organizations. Moreover, the schools differ in the standards that guide these interactions, as well as in the norms that bound professional and academic pursuits. The policy accordingly delegates to the schools substantial authority to tailor implementation to their particular conditions, and, in particular, to adopt more stringent, but not less stringent, terms and procedures when deemed necessary.

It is imperative that in implementing this policy Harvard and its schools commit themselves to creating an effective and credible system for the internal, confidential disclosure, review, and resolution of financial conflicts of interest. Equally important, such a system must operate fairly and without unduly constraining faculty interactions with outside organizations and communities, which help to fulfill the University's obligation to serve society.

FINANCIAL CONFLICTS OF INTEREST

The concept of a conflict of interest can be understood by reference to *primary* and *secondary* interests. The Institute of Medicine of the National Academies of Sciences states: *A conflict of interest is a set of circumstances that creates a risk that professional judgments or actions regarding a primary interest will be unduly influenced by a secondary interest.*[1]

Every faculty member shares with the University a *primary* interest in preserving and furthering the University's core missions and values. Paramount among these missions and values for the purposes of this policy are assurance of personal and institutional integrity in the conduct of all academic duties; pursuit and communication of

---

[1] IOM (Institute of Medicine), 2009, *Conflict of Interest in Medical Research, Education, and Practice*, Washington, D.C.: The National Academies Press *46*.

truth; independent, objective, and ethical scholarship and research; accountability for actions and conduct; and preservation of the University's standing as an institution worthy of public confidence and trust.

In the course of academic life, as is true in all professions, a faculty member inevitably holds *secondary* interests as well. Such secondary interests are many and ubiquitous. For the most part, they are legitimate and, indeed, are inherent in the professions, well recognized, and managed by sundry professional standards and behavioral norms. The prospect of personal financial gain is one such secondary interest, but there are many others of a nonfinancial nature, including, for example, securing career advancement, advancing the interests of friends and relatives, or winning accolades from peers or highly competitive prizes. Some secondary interests, such as obtaining and renewing sponsored research funding or being the first to publish research findings, may even be argued as necessary for faculty members to support the core missions of the University. Notwithstanding, such interests remain secondary because they may on occasion misalign or conflict with a faculty member's and the University's shared primary interests.

This policy confines its focus to *financial* conflicts of interest. In part, this is because financial conflicts of interest are discernible, measurable, volitional, manageable, and well understood by the public. In addition, they often generate deep public concerns, especially when recognized in organizations or individuals perceived to hold fiduciary positions or relationships of public trust. However, in focusing on financial conflicts of interest, this policy does not intend to minimize the importance of nonfinancial conflicts, which can and do influence professionals' judgments, choices, and decisions.[2]

We define an individual financial conflict of interest as follows:

> *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.*

A financial conflict of interest is a matter of objective circumstance, and, therefore, a distinction between "apparent" and "actual" conflicts of interest is not useful. A conflict of interest does not depend on the character or actions of the individual. It exists (or does not

[2] This Policy allows Schools the discretion, in their implementation plans, to require the disclosure of certain significant non-financial outside interests (for example, substantial pro bono involvement), in order to further the goal of protecting the reputation for scholarly integrity of the University, School and individual faculty members.

exist) regardless of whether it is operative, that is, whether it is in fact influencing an individual's judgment or actions. *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.*

B. DEFINITIONS and SCOPE OF APPLICATION

Except where otherwise specified, this Policy applies to all holders of Faculty or teaching appointments in the University. Investigators applying for or receiving funding from the United States Public Health Service (PHS) (including the National Institutes of Health) are subject to additional disclosure requirements as described in Section E and Appendix A of this Policy.[3] Other sponsors may have their own conflict of interest policies with which individuals also may be expected to comply.

The schools have discretion to decide the extent to which holders of part-time or visiting faculty or teaching appointments, or post-doctoral fellows, shall be subject to disclosure obligations under this policy. However, the schools are encouraged to require that visiting faculty whose appointments require them to participate in academic duties within the school for six months or more comply with this Policy, and regardless of the length of time of their participation in duties at Harvard, visiting and part-time faculty internally, confidentially disclose financial interests prior to teaching on a topic that is closely related to their financial interests.

Equity
"Equity" means stock, stock options, warrants or other ownership interest.

Family Member
"Family member" means spouse and dependent children. So far as the financial interests of family members bear upon the application of this policy, a faculty member must affirmatively make inquiry into, and shall be presumed to know of, the financial interests of family members as herein defined.

[3] "Investigator" for purposes of compliance with the conflict of interest regulations of the Public Health Services is broader than the class of faculty and holders of teaching appointments under this policy. For PHS purposes, "investigator" is "the Project Director/Principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, including persons who are subgrantees, contractors, collaborators, or consultants. " Therefore, in order to comply with PHS regulations, it may be necessary, in specific grants, for post-doctoral candidates, fellows and even graduate students, to complete internal disclosures under this policy. See 42 C.F.R. 50.602 (definition of "investigator").

Fiduciary or Management Role
"Fiduciary or management role" means service as an officer, director or service on an advisory board (including scientific advisory boards), whether paid or unpaid. Investigators may need prior approval from the Dean before assuming such responsibilities. "Fiduciary or management role" does not mean service on an editorial board. In their implementation plans, schools may extend this requirement to include service on the board or advisory panel of a not for profit entity.

Institutional Responsibilities
"Institutional responsibilities" means an individual's professional responsibilities on behalf of Harvard. Such responsibilities include, but are not limited to: research, research consultation, teaching, professional practice, institutional committee memberships, and service on committees or panels such as research ethics committees (e.g. Institutional Review Boards, Institutional Animal Care and Use Committees) and other bodies monitoring the conduct of research.

Internal Confidential Disclosure
"Internal confidential disclosure" as opposed to *public disclosure*, means the provision by individuals of information about their outside financial interests related to their institutional responsibilities *internally* to institutional officials and bodies designated in their school's implementation plan.

Investigator
"Investigator" means the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research.

Related Outside Entity
School policies may use a different definition of "related outside entity" when a compelling reason exists to do so, and with the prior approval of the University Standing Committee on Financial Conflicts of Interest.

"Related outside entity" means an entity in which a person has a significant financial interest that may, or may reasonably appear to an outside observer, to influence the discharge of teaching, research, or other University-related responsibilities. In determining relatedness, individuals should employ a standard of common sense, and when in doubt, disclose. Examples of entities that might be related are those:

(1) whose products, services or activities are related to the areas of a faculty member's or an investigator's teaching or research;

(2) that fund research in a faculty member's or an investigator's area of academic interest;
(3) that own or have rights to develop intellectual property that is the subject of research in which a faculty member or an investigator participates;
(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 a faculty member's or an investigator's teaching or research activities;
(6) that furnish products or services to the University through a contractual process in which a faculty member or an investigator participates in any way;
(7) that propose to enter a licensing agreement with the University with respect to technology invented by the faculty member or investigator;
(8) that act as a legal or *de facto* agent for any outside entity engaged in any of the above activities.

Significant Financial Interest

School policies may use a different definition of "significant financial interest" when a compelling reason exists to do so, and with the prior approval of the University Standing Committee on Financial Conflicts of Interest.[4]

"Significant Financial Interest" includes, but is not limited to, (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. "Financial compensation" does not include, for example, interests of any amount in diversified financial holdings, or royalties or other remuneration paid by Harvard.

Students

"Students" means students, trainees, and post-doctoral fellows.

[4] In their determination of what constitutes a significant financial interest, such interests should be evaluated and managed to determine the risks that potential conflicts arising from those interests would pose to objective and independent scholarship, to the well-being of human research participants and animal subjects, to the integrity of the research training environment, and to individual and institutional reputations. Since mounting evidence from the behavioral and neurosciences strongly indicates that even token gifts and payments can affect judgments, choices, and decisions at a level beneath awareness, this policy urges the Schools to take this evidence into consideration in developing their Implementation Plans.

C. GOVERNING PRINCIPLES

This policy rests upon principles that are central to the role of universities and academic scholars. These principles should guide the conduct of Harvard faculty and inform the interpretation and application of the policy.

1. Society grants special privileges to universities and their faculty in return for their contributions, especially in fulfilling their role as independent arbiters of knowledge. With these privileges come special responsibilities and standards of conduct.

2. Societal trust in the University depends upon the independence, integrity, and transparency of the University's endeavors, and the University must, accordingly, practice responsible and vigilant self-governance to ensure that it remains trustworthy.

3. The University's missions as well as the public interest are served by responsible interactions between faculty members and others (including government, business, and other organizations and individuals), with a view toward stimulating and nurturing research and education, the development and beneficial application of policies and technologies, and the pursuit of other scholarly and educational activities.

4. Independent inquiry and the publication of scholarly findings are vital to the integrity and objectivity of research.

D. OPERATING PRINCIPLES

<u>Avoidance of financially conflicting interests</u>

The educational and research activities of the University should be motivated primarily by a concern for the advancement of knowledge and the pursuit of truth. Accordingly,

1. **Faculty members should not permit outside activities and financial interests to compromise their primary commitment to the missions of the University and to the highest intellectual and ethical standards in discharging their academic responsibilities.**

2. **Faculty members should refrain from actions that could reasonably bring discredit upon Harvard and their own academic and scholarly integrity, and they should avoid circumstances that reasonable observers would believe create an undue risk that the prospect of direct or indirect personal financial gain could inappropriately influence faculty members' judgment or actions in fulfilling their University duties.**

These Operating Principles echo core ethical norms articulated in diverse University and school policies[5] and are intended to complement the Conflict of Interest and Code of Ethics provisions of the University's *Strategic Procurement Guide* (http://vpf-web.harvard.edu/ofs/procurement/pdf/harvard_procurement_manual.pdf)

<u>Compliance with laws</u>

3. **Faculty members must comply with all state and federal requirements applicable to financial interests in research or other academic activities, including but not limited to licensure and professional conduct standards, financial disclosure requirements, laws concerning "finder's fees" for research subjects, prohibitions against insider trading, and statutes and regulations concerning conflicts of interest.[6]**

[5] For example, University policies that govern the outside interests and activities of faculty members include the "Statement on Outside Activities of Holders of Academic Appointments" (*as voted by the President and Fellows of Harvard College, effective July 1, 2000*) and "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*). See also "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 vote of the FAS on October 29, 1987 and May 2, 1995, and amended by vote of the Faculty Council on November 15, 2000*).

[6] The U.S. Office of Management and Budget's Circular A-110 requires in Section 42 that not-for-profit entities receiving federal awards, as well as entities (not-for-profit or commercial) that are sub-awardees or subcontractors, must have written standards of conduct governing all employees engaged in the award and administration of contracts that address conflicts of interest. In addition, several agencies have promulgated regulations that address conflicting financial interests in research and contracting, including the U.S. Public Health Service (42 CFR Part 50 and 45 CFR Part 94), and the Food and Drug Administration (21 CFR Part 502). The National Science Foundation has essentially adopted the 1995 PHS rules in NSF Award and Administration Guide, Chapter IV.A (NSF 10-1), http://www.nsf.gov/pubs/policydocs/pappguide/nsf10_1/aag_4.jsp#IVA).

Free inquiry and intellectual exchange

The free and open exchange of ideas and the results of scholarly activities is the essence of academic freedom and is fundamental to the integrity of the University as a community of scholars.

Faculty members must foster an atmosphere of academic freedom by promoting the free, open, and timely exchange of results of scholarly activities. Financial conflicts of interest cannot be permitted to undermine independent inquiry or uncensored publication of ideas and findings.

4. **Agreements with commercial enterprises that sponsor academic work must comply with the University's "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*).

5. **Faculty members must not be induced by financial interests to (1) give outside sponsors or other organizations or individuals authority to direct their studies or to restrict or unreasonably to delay[7] the release or publication of research results, or (2) participate under the aegis of the University in scholarly activities whose existence, methods, purpose, or results are held confidential. Although this second prohibition does not apply to projects undertaken as part of a faculty member's permissible outside activities, faculty should avoid entangling outside projects with their academic duties in ways that could, among other consequences, subject members of the University community to improper constraints (for example, by assigning students or trainees to work for academic credit on outside projects that require their ideas or scholarly products to be held in confidence).**

Not infrequently, outside entities – for example, companies or individuals uniquely in control of information or materials required for a scholarly investigation or for preparation of case studies deemed valuable for classroom instruction – retain privacy interests or property rights in the information or materials throughout the course of the investigation. To respect privacy interests, it is often necessary to provide the source of non-publicly available information the right of prior review of the final work product.

---

[7] See Office for Sponsored Programs, Policy on Publications (revised November 2011), http://osp.fad.harvard.edu/content/policy-publications (allowing sponsors, at most, only 30 to 60 day periods for pre-publication review and comment).

Harvard University's Sponsored Programs Policy on Publications (Revised November 2011) therefore allows sponsors, at most, 30 to 60 days for the review of manuscripts and other materials prior to publication or oral disclosure.

If there is a financial relationship between the faculty scholar and the source of the information or materials, a financial conflict of interest exists, and the circumstances must be disclosed, reviewed, and adjudicated according to the school's plan for implementation of this policy.

The obligation of faculty to promote the free, open, and timely exchange of the results of scholarly activities should not be construed to be inconsistent either with protections of individual or group privacy and confidentiality required by regulation, ethical standards, or professional codes of conduct, or with legal protections accorded intellectual property and confidential or proprietary information.

<u>Instruction and advising of students</u>

"The student-faculty relationship lies at the heart of the academic enterprise."[8] A faculty member's outside financial interests should not adversely influence his or her instruction, guidance, or supervision of students, trainees, or post-doctoral fellows. Academic assignments to students, trainees, and post-doctoral fellows should principally serve their interests in learning, self-development, and satisfaction of requirements for academic advancement.

6. **Faculty should not assign students, trainees, or post-doctoral fellows to participate in research projects or other scholarly projects that constrain or could constrain their ability freely to discuss, defend, and publish their research.**

7. **Without the prior approval of the school Dean, no faculty member may assign any student, trainee, or post-doctoral fellow to any research project or other scholarly project in which the faculty member or a member of his or her family has a financial interest directly or through an outside entity.**

Further, a faculty member must ensure that the assigned work of students, trainees, and post-doctoral fellows is not exploited in service of the faculty member's outside activities.

---

[8] "Principles Governing Commercial Activities of Harvard University," *as approved by the Corporation on Sept. 17, 2001*.

8. **Faculty members should not be employed by or enter into a commercial relationship with a current student or an entity substantially controlled by the student. A commercial relationship for these purposes includes, but is not limited to, the ownership of stock, stock options, or other equity.**

Operating Principles 6-8 draw a distinction between faculty members' assignment of students to projects as part of the students' academic programs and their hiring of students to work on faculty members' academic, consulting, or other outside activities.

The subject matter of a faculty member's instruction of and assignments to students, trainees, and post-doctoral fellows (referred to collectively throughout the remainder of this annotation as "students") may overlap with the subject matter of the faculty member's outside consulting or related activities. In such instances, faculty members must exercise special care to avoid exploiting student work or subordinating the prerogatives and interests of their students to such outside activities. To this end, faculty members should be transparent with students about their activities with and obligations to outside entities that could benefit from the work or ideas of their students. Similarly, students should have ready access to information about faculty members' sources of funds that support the students' research or scholarly work.

This Operating Principle's restriction on assigning students to research projects in which a faculty member has a financial interest does not include research projects in which the faculty member's "financial interest" is entirely aspirational and speculative. For example, at the point of disclosing a new technology to the Office of Technology Development where the commercial value of the invention is largely unknown, involving students in further investigations of the technology that serve their training objectives would generally not be problematic. At some point in the commercial development of a licensed technology, however, the inventor may realize a sufficient financial interest to trigger the requirement of approval by the Dean prior to assigning students to follow-on research. Because such "trigger points" will vary among different technologies and disciplines, responsibility for defining them is appropriately delegated to the cognizant schools. If uncertain about the application of this Operating Principle, faculty members should seek advice and/or approval from their school Dean.

9. **Faculty members should not, directly or through an outside entity under their substantial control (or under the substantial control of a family member), employ or enter into commercial relationships with students who are concurrently enrolled in their classes or for whom they serve as assigned faculty advisors.**

This restriction does not apply to the practice of hiring students to assist with a faculty member's academic duties, for example, as research or teaching assistants, nor does it prohibit a faculty member from hiring students to assist in the preparation or editing of a scholarly text. (Note, however, that this Operating Principle does prohibit the *assignment* of students to work on such tasks without the prior approval of the Dean.) In addition, when students' course grades are determined solely by blindly graded exams, the school may determine that faculty members' employment of students concurrently enrolled in such courses offers the students greater benefits than risks and is generally permissible.

Supervisory responsibility

10. **Faculty members in positions of academic seniority or administrative authority must maintain the highest level of ethical integrity in carrying out their supervisory responsibilities.**

11. **A faculty member's outside financial interests should not influence his or her supervision, mentoring, evaluation, or direction of other faculty or staff.**

12. **Faculty must not exploit junior faculty or staff in service of the faculty members' outside activities or otherwise to realize personal financial gain.**

Use of University resources

13. **Faculty members may not use University resources, including confidential information or – other than in a purely incidental way – facilities, personnel, or equipment to support their outside consulting activities or for any other purposes that are unrelated to the education, research, scholarship, and public service missions of the University.**

14. **Use of the Harvard name by faculty members must comply with regulations set forth in existing University policies.[9]**

15. **Use for personal profit of unpublished information emanating from University research or other confidential University sources, or assisting**

[9] See, in particular, the University's "Statement on Outside Activities of Holders of Academic Appointments" (*voted by the President and Fellows of Harvard College*, *effective July 1, 2000*) and "Policy on the Use of Harvard Names and Insignias" (*voted by the President and Fellows of Harvard College, February 9, 1998)*.

an outside organization by giving it exclusive access to such information, is prohibited.

16. **A faculty member generally may not, as part of a sponsored project or other University project or activity, seek to subcontract with, or seek to enter into any other agreement for the purchase of goods or services with, an entity in which s/he or a family member has a significant financial interest or holds a fiduciary or management role.**

These Operating Principles acknowledge that different schools and academic disciplines may vary within a reasonable range in their interpretation of incidental usage. What is acceptable in a given school may legitimately depend upon the nature of the resource (e.g., office or lab space, production facilities, major equipment), whether reimbursement of costs to the School is required, the extent to which the outside activities benefit the school, and so forth.

As a general matter, faculty should not abuse their access to or use of University resources. Resources shared with other members of the Harvard community (e.g., library materials, studios, support staff) must be available for uses related to University activities ahead of uses related to a faculty member's outside activities.

Inappropriate use of University resources includes the following:

- More than incidental use of University staff on a faculty member's outside consulting or business activities without prior approval by the school Dean.

- Granting outside entities access to Harvard resources or services for purposes unrelated to sanctioned University activities.

- Unilaterally appropriating patentable inventions or protectable software rather than disclosing such products to the Office for Technology Development for its determination of ownership in accordance with University policy. *See* the University's "Statement of Policy in Regard to Intellectual Property," (*amended, restated, and renamed by the Corporation on February 4, 2008*).

- Using for personal gain, or granting others unauthorized access to, confidential information acquired through conduct of University business or research activity, including, for example: medical, personnel, or security records of individuals; proprietary knowledge about the corporate affairs or business dealings of the University; and information from public agencies concerning contract awards or regulatory decisions in advance of their public release date.

- Providing preferential access to research results, materials, or products generated from University teaching or research activities to an outside entity for personal financial gain. (This would not preclude appropriate licensing arrangements for inventions, or consulting on the basis of sponsored project results where there is significant additional work or expertise involved.)

In order to avoid the appearance of self-dealing and potential conflicts in selecting, overseeing and monitoring subcontractors and vendors, faculty members should not direct subcontracts or vendor/purchase agreements to entities in which they or their immediate family members hold a fiduciary role or significant financial interest. In extraordinary circumstances, an exception may be made to this rule, but only with the written approval of the faculty member's dean and the Office of the Provost, and with disclosure to the appropriate sponsors and funders.

E. DISCLOSURE REQUIREMENTS

<u>Internal disclosure of financial interests</u>

Important benefits accrue from requiring that faculty internally and confidentially disclose, for review by disinterested school officials, all significant financial interests.[10] Such disclosure relieves the faculty member of the burden of making difficult discriminations in deciding whether a financial conflict of interest exists and how to resolve or manage it; it protects the reporter and the institution from allegations of undisclosed conflicting financial interests; and, above all, it enables the institution to identify and respond in timely fashion to conflict situations.

Accordingly all **faculty members, and any investigator** applying for or receiving funding from the United States Public Health Service (PHS) (including the National Institutes of Health and the Centers for Disease Control and Prevention) **must submit, in the format prescribed by their school, an internal, confidential disclosure of their and their family members' *significant financial interests* in the preceding twelve months in any *related outside entity*. In determining relatedness, faculty and covered investigators should apply a standard of common sense, and when in doubt, disclose.**

---

[10] In their implementation plans, schools may require the disclosure of certain significant non-financial outside interests (*see footnote 2, above*).

All faculty members, and any investigator applying for or receiving funding from the PHS, must update disclosed information (e.g. a change in value of a previously disclosed interest) at least annually and:

- **Within 30 days of the discovery or acquisition of a new significant financial interest; and**
- **Prior to:**
    - **Accepting gifts**
    - **Submitting an application for a sponsored project**
    - **Initiating a technology licensing agreement**

Annual disclosures should include sufficiently detailed information for a disinterested reviewer to appraise the risk of conflicts arising from the faculty member's, or his or her family members', outside financial interests. Ordinarily, for any disclosed financial interest, this information should include the identity of the entity in which the faculty member or his or her family members hold a financial interest, the nature of the interest, any outside professional activity that was or will continue to be associated with the financial interest (e.g., service as a consultant, member of an advisory committee, or manager or fiduciary), and the size or value of the interest in a preceding 12-month period.

Individuals who have no financial interests to disclose shall certify to that fact in writing. In addition, annual disclosures should include an affirmation that the faculty member is aware of the University's Financial Conflict of Interest Policy and his or her school's Implementation Plan requirements and is in compliance with them.

School Deans (as well as senior officers and administrators of the University) shall file their own annual disclosures with the Office of the General Counsel as prescribed in the Harvard University Policy on Conflicts of Interest and Commitment for Senior Officers and Administrators, in addition to filing any disclosures as required by this policy.

All financial disclosures described herein shall be maintained in a secure format, 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.[11] Disclosed information, either as it pertains to an individual or in aggregate, will be used (a) to assure compliance with

[11] 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.

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.[12]

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

School Implementation Plans should provide guidance for the retention of disclosures and related records that is consistent with *Harvard University's General Records Schedule* (http://grs.harvard.edu/).

Because related outside professional activities that involve managerial or fiduciary responsibilities may give rise to irremediable financial conflicts of interest, and because unwinding these relationships can be awkward and difficult, it is strongly recommended that school Implementation Plans require approval by the Dean before faculty assume such responsibilities.

If, after the submission of an annual disclosure, there is a material change in a faculty member's financial interests, the faculty member should update his or her disclosure in writing to reflect the change as soon as possible. Even if prior approval by the Dean is not required, faculty members, when feasible, should disclose expected changes or newly anticipated financial interests before they occur to enable meaningful evaluation by responsible school officials.

No sponsored research proposal should be submitted to the Office of Sponsored Programs (or to Sponsored Research Administration offices in the Schools of Public Health and Medicine), or, in the case of research to be covered by an industry-sponsored agreement, to the Office of Technology Development unless each faculty member participating in the research project, and – in the case of proposals for PHS funding – any investigator , has certified to having filed an accurate and up-to-date annual disclosure. The OSP (or the SRAs) will not transmit such a proposal and the OTD will not sign such an agreement without such certifications.

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

F. REVIEW AND MANAGEMENT OF SIGNIFICANT FINANCIAL INTERESTS

This policy provides substantial discretion to the schools to determine which disclosed interests and activities require institutional management and the detailed specifications of that management, and which require the Dean's prior approval.

Each school shall adopt an Implementation Plan establishing procedures to ensure timely review of their faculty's annual internal, confidential disclosures of financial interests, to ensure the appropriate elimination, reduction, or management of financial conflicts, and to ensure that financial conflicts and plans for their management are communicated in a timely manner to faculty members and institutional officials and bodies with a need to know (conflict of interest committees, Institutional Review Boards, Institutional Animal Care and Use Committees, Office for Technology Development, Office of Sponsored Programs, etc.).

Each school's Implementation Plan shall comply with all state and federal requirements applicable to conflicts of interest.

Each school's Implementation Plan, and any subsequent changes, shall be submitted to the standing University-wide Committee on Financial Conflicts of Interest for review and approval.

Each school Dean, or other school official or committee designated by the Dean, shall be responsible for reviewing annual internal, confidential disclosures of financial interests, and subsequent updates to such disclosures, and determining whether such interests create conflicts of interest under the University Policy, the school's Implementation Plan, or other applicable laws and regulations. As further described below, if a financial conflict of interest is found to exist, the school Dean, designated official or committee must design and implement a plan to manage or eliminate the conflict. Reviewing officials or committee members who have a conflict of interest in reviewing disclosed information shall immediately recuse themselves, inform their superior, and request that the review be performed by a disinterested alternate. (Where a school Dean has a conflict of interest, the Dean shall inform the Provost or designee, who may designate an alternate from within or without the school to conduct the review.)

The review and disposition of instances of financial conflicts of interest is an exercise in the assessment and management of risks to scholarly integrity, to the well-being of human research participants or animal subjects, to educational obligations to students and trainees, and to individual and institutional reputation. The assessment should be fact-driven, case-specific, context-sensitive, and informed by the principles of the University's Financial Conflict of Interest Policy, the school's Implementation Plan, and applicable laws and regulations. Among the circumstances to be considered are the nature of the academic activity, the magnitude of the financial interest and the degree to which it is related to the academic activity, the extent to which the academic activity could be directly and substantially affected by the financial interest and vice versa, the likelihood and severity of potential harm to involved individuals and to the University, and the consequences of prohibiting or limiting the conflicted faculty member's participation in the activity.

In circumstances involving high risk and sensitivity, schools may choose to apply a presumption that a financially conflicted faculty member should not participate (or not participate in a significant way) in the proposed academic activity. The school may permit the presumption to be rebutted by evidence of compelling circumstances, that is, evidence that the consequences of prohibiting the conflicted faculty member's participation in the academic activity outweigh the identified risks. This approach may be considered especially when (1) the proposed academic activity involves human research participants or animal subjects, or (2) a faculty member with an equity interest in a privately-held corporation proposes to conduct research sponsored by the corporation that could enhance the value of the equity interest.

Whenever a Dean or designated reviewing entity determines that a financial conflict of interest exists, the school must respond by *eliminating*, *reducing*, or *managing* the conflict and must generate a written record of its response. A conflict can be **eliminated** by requiring that the faculty member divest the conflicting financial interest, or refrain from participating in the conflicted academic activity. In some instances, it may suffice for the faculty member to **reduce** his or her financial interest to a level that the school deems acceptable for the academic activity in question. In other instances, a conflicted academic activity may go forward under a credible plan to **manage** the conflict in a way that acceptably minimizes the associated risks (for example, by modification of the research plan; by a change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the activity).

Whenever a school determines that a conflicted academic activity should be allowed to proceed and the disposition requires creation of an oversight or other management plan, the plan must be agreed to and signed by the conflicted faculty member and a copy included in the written record. The written record shall be shared with school and University officials with a need to know, and schools shall review all oversight and management plans periodically.

School Deans should be held accountable for effective enforcement of this policy and their own Implementation Plans. The University Conflict of Interest Committee is available to assist Deans and their designated conflict officers and committees in implementing their school plans and in adjudicating any specific case of financial conflict of interest.

Public Disclosure

Public disclosure is the bedrock of conflict of interest policies within and without academe. Public disclosure in no way cures a financial conflict of interest but is an essential step in responding to such conflicts. In making a financial interest in a related outside entity publicly known, disclosure obviates opportunities for corrosive accusations of concealment detrimental not only to the individual but to institutional and sector credibility. In addition, disclosure enables listeners to discount the credibility or influence of the speaker's opinion or advice.

When conflicts of interest are identified and handled, see *F. Review and Management of Significant Financial Interests* above, public disclosure will be an element of many management plans. Additionally, faculty members must make public disclosures of financial interests in related outside entities and sources of support when reasonable members of the audience would give weight to those interests in assessing the opinions, advice, or work they are presenting. Faculty members are also expected to comply with the disclosure requirements of their professional journals and societies.

Public disclosure of financial interests in related outside entities is particularly important when faculty members are sought as experts to inform the public on matters of concern and to help shape public policy.[13]

School Implementation Plans should reflect these standards and, if a school chooses, may require the public disclosure of *all* financial interests related to a faculty member's institutional activities, regardless of whether such interests are determined to be *in conflict* with the related activities.

The above provisions are not intended to compromise professional duties of confidentiality or violate confidentiality protections dictated by law or professional codes of conduct.

[13] When addressing the public, faculty members usually act in their individual capacity and, in many instances, are engaged in the "private" sphere of their permissible consulting activities. While faculty members will not be acting on behalf of the University in any of these roles, the public ordinarily will not appreciate this distinction. Accordingly, actions in that sphere that bring discredit upon the faculty member have the potential to injure the University's reputation as well. The expectation of transparency is justifiably high when Harvard faculty members serve as expert advisers to governmental entities or to the public directly. Faculty in such roles should be mindful of this principle and publicly disclose financial interests and sources of financial support that could be seen as biasing.

Faculty members may be required by their schools to make other public disclosures concerning their financial interests. As a precondition to participating in research in which a faculty member has a conflicting interest, a school Dean (or other official or entity responsible for devising a management plan) may require a faculty member to disclose his or her conflicting interest: (a) to all participating investigators and appropriate members of the laboratory or research group, students, and trainees; (b) to prospective students, trainees, and new faculty before such individuals make a decision to join the laboratory or research team, (c) to funders and sponsors of the research; (d) to human research participants, as determined by an Institutional Review Board; (e) to state and federal officials, as required by statute or regulation; or (f) to other parties as deemed appropriate in the circumstances (e.g., advisees, students, general public). A comprehensive response to a determination that a conflict of interest exists may also require elimination, reduction, or credible independent management of the conflicting interest.

A school Dean may determine on specific academic grounds that, in extraordinary cases, public disclosure of a financial interest related to a particular academic activity or class of activities is inadvisable.

G. SANCTIONS

School Implementation Plans shall provide for appropriate sanctions and remediation for willful failures by faculty members to comply with the University Policy on Individual Financial Conflicts of Interest, school Implementation Plans, and applicable laws and regulations. Knowing failures to file timely internal disclosures of financial interests, willful submission of materially incomplete or inaccurate disclosures, and failures to adhere to conflict management plans are unacceptable and shall result in such sanctions as the school Deans, in consultation with cognizant school committees, and with the Provost or designee as appropriate, deem warranted.

The University and the schools shall communicate to all faculty the requirements of the University's Policy on Individual Financial Conflicts of Interest and schools' Implementation Plans on a periodic basis that will sustain understanding and awareness.

Every member of the University faculty should view with utmost seriousness his/her obligation to disclose outside financial interests fully, accurately, and in a timely manner, and to be vigilant in protecting the independence and objectivity of his/her scholarly activities as well as his/her service as an expert advisor to the public.

H. UNIVERSITY OVERSIGHT

The Office of the Provost, in consultation with the University Committee on Financial Conflicts of Interest, and with the Office of General Counsel as appropriate, shall be responsible for overseeing the University-wide implementation of this policy and assuring ongoing compliance with its terms.

The Office of the Provost and the University Committee on Financial Conflicts of Interest shall provide advice to Deans concerning the interpretation and application of this policy. In addition, Deans are encouraged to consult with the University Committee on Financial Conflicts of Interest when dealing with a financial conflict of interest of unusual significance due to its complexity, magnitude, notoriety, or precedential impact, or that presents a significant new policy issue.

In cross-faculty and inter-school collaborations for research and teaching, and in formal inter-faculty initiatives, there will be occasions when implementation plans, standards and processes of different schools may apply concurrently and even may conflict. In general, in the first instance, faculty should seek to abide by the policy of the school in which they have their primary academic appointment, and faculty participating in interfaculty initiatives presumptively should follow the implementation plans of the school with which they are primarily affiliated. In cases in which cross-faculty and inter-school activities implicate differing school implementation plans, or in which a faculty member may be subject to two plans by virtue of a joint appointment, the designated institutional officials for the schools implicated should consult with one another, with a general goal of selecting *one* implementation plan with which individuals involved must comply. Schools and other entities (e.g. inter-faculty initiatives) may consult with the Provost's Office and/or the University Committee on Financial Conflicts of Interest for guidance in complex matters of this type.

Each school shall submit for review by the University Committee on Financial Conflicts of Interest an annual report describing identified conflicts of interest, how they were resolved (including the terms of management plans), and any sanctions imposed. Such reports may be submitted without personal identifiers.

The Provost's office shall report annually to the Joint Committee on Inspections on the status of this policy and its implementation. The Office of the Provost , in conjunction with University Risk Management and Audit Services, the University Committee on Risk Management, and University and school compliance officials, shall periodically audit each school's reports, the school's review practices under its Implementation Plan, conflict management plans, agreements with outside sponsors of academic activities, and other relevant records in order to (1) evaluate compliance with this policy within schools, (2) assess the consistency of compliance and the coherence of practices within and across schools, and (3) develop recommendations for modifying the University Policy and School Implementation Plans and practices, educate faculty and administrators, and otherwise enhance the robustness of the University's strategies for dealing with financial conflicts of interest. Audit summaries shall be shared with the University Committee on Financial Conflicts of Interest. Each school shall be audited within the first three years of adoption of this Policy and, thereafter, at least once every five years.

APPENDIX A

Requirements for Disclosing Travel for Individuals Receiving Funding from the U.S. Public Health Service (including the National Institutes of Health)

Any investigator receiving funding from the U.S. Public Health Service (PHS) must disclose to their Dean or designee 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.

School Implementation Plans will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. Schools may require that Investigators disclose their planned or anticipated reimbursed or sponsored travel in a prospective manner (e.g. over the next twelve months) at the time of the annual update of financial interests, with a requirement to update the travel disclosure annually. However, Investigators must disclose new (unanticipated) sources of travel within 30 days of such travel.

The school's Dean or designee will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a financial conflict of interest in regard to the PHS-funded research.