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

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 reporting them, that reported 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 greater 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 reporting, reviewing, and resolving 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 commitment, indeed, obligation, to serve society.

Except where otherwise specified, this policy applies to all holders of faculty or teaching appointments in the University.[1]

B. FINANCIAL CONFLICTS OF INTEREST

The concept of a conflict of interest can be understood by reference to *primary* and *secondary* interests. A generic definition recently put forth by 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*.[2]

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 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,

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1 For the applicability of this Policy to holders of visiting faculty or teaching appointments, see Operating Principle 8, Annotation i in Part D below.

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

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 like all secondary interests, whatever their nature, 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 nonfinancial conflicts of interest are (1) harder to discern, evaluate, and measure, (2) in many respects less volitional, and (3) less susceptible of regulation. In contrast, 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.

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.**

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

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 towards 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

1. **Avoidance of financially conflicting interests. 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, 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. They 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.**

   Annotation

   This Operating Principle echoes core ethical norms articulated in diverse University and School policies. 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 votes of the FAS on October 29, 1987 and May 2, 1995, and amended by vote of the Faculty Council on November 15, 2000*).

2. **Compliance with laws. Faculty members are expected to 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.

Annotation

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 C.F.R. §§ 50.601, *et seq*., and 45 C.F.R. §§ 94.1 *et seq.*), and the Food and Drug Administration (21 C.F.R. §§ 502 *et seq.*). The National Science Foundation has essentially adopted the 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). Although the reach of the PHS and NSF regulations is limited to research sponsored by those agencies, it has been common practice among research universities, including Harvard, to apply these rules to all research irrespective of sponsor.

3. **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.**

Annotation

a. 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*).

b. 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 delay 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 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).

c. 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.

d. 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, or even approval, of the final work product. Similarly, to accommodate property rights, institutional research policies allow sponsors a reasonable time (generally, 30 – 60 days) to review research manuscripts "for potentially patentable material or to ensure that the sponsors' confidential or proprietary information is not being disclosed." *See* "[FAS] Guidelines for Research Projects Undertaken in Cooperation with Industry" (*voted by the President and Fellows of Harvard College, October 3, 1983, and revised April 3, 2000*). *See also* "Office for Sponsored Programs Handbook," available at http://vpf-web.harvard.edu/osp/quick_links/policies, and the "Faculty of Medicine Statement on Research Sponsored by Industry" (*October 1983; amendments adopted January 1996*). These practices do not offend this Operating Principle. However, 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 reported, reviewed, and adjudicated according to the School's plan for implementation of this policy.

4. **<u>Instruction and advising of students</u>. "The student-faculty relationship lies at the heart of the academic enterprise."[1] 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. 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. 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.**

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

Annotation

a. The term "family member," as used throughout this policy, means any relative who lives in the same household as a faculty member. 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 defined above. Although no presumption of knowledge shall apply with respect to the financial interests of relatives not living in the same household, if a faculty member is or becomes aware that a non-cohabitating first-degree* relative holds a financial interest that is addressed by this policy, it is covered by this policy. Accordingly, faculty members should be sensitive to situations where they learn of non-cohabitating relatives' financial interests, and, if in doubt about their obligations in such situations, should seek guidance from their School Dean.

* A first-degree relative means a spouse, parent, sibling, or child.

b. This Operating Principle draws a distinction between faculty members' <u>assignment</u> of students to projects as part of the students' academic programs and their <u>hiring</u> of students to work on faculty members' academic, consulting, or other outside activities.

c. 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.

d. 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 decanal approval 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.

e. 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.

f. 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.

5. **Supervisory responsibility. Faculty members in positions of academic seniority or administrative authority must maintain the highest level of ethical integrity in carrying out their supervisory responsibilities. A faculty member's outside financial interests should not influence his or her supervision, mentoring, evaluation, or direction of other faculty or staff. Faculty must not exploit junior faculty or staff in service of the faculty members' outside activities or otherwise to realize personal financial gain.**

6. **Use of University resources. 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. Use of the Harvard name by faculty members must comply with regulations set forth in existing University policies.[1] Use for personal profit of unpublished information emanating from University research or other confidential University sources, or assisting an outside organization by giving it exclusive access to such information, is prohibited.**

[1] **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)*.**

Annotation

a. This Operating Principle acknowledges 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.

b. 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.)

7. **<u>Ad hoc reporting of transactional financial relationships</u>. Before the University will approve certain transactions with an outside entity that involve a faculty member's academic activities, faculty members must report to their School, and to cognizant University officials when required by University policies, whether they or members of their family have financial relationships with the outside entity. The referenced**

transactions are gifts, sponsored projects, technology licensing arrangements, and certain procurements. "Financial relationships" include but are not limited to (1) consulting, employment, managerial, and fiduciary relationships, and (2) equity and other financial interests in amounts deemed to be of concern by School implementation plans.

Annotation

a. In this Operating Principle and the annotations that follow, references to "University" are intended to encompass University-affiliated entities, such as affiliated teaching hospitals, in which faculty may pursue academic activities that are governed by University and/or School policies.

b. Applicable Harvard University policies referenced in this Operating Principle include: the "Policy Statement Regarding Application of Harvard University's Conflict of Interest Policies to the Granting of Licenses" (*as most recently amended by authority granted by the Corporation on February 4, 2008*), which calls for reporting to the Office of Technology Development of "personal financial relationships" and "Close Financial Interests;" and the "Harvard University Policy on Conflicts of Interest and Commitment for Senior Officers and Administrators," which requires senior officials, "at any time when the Senior Official becomes aware of them," to report conflicts of interest, defined as "financial or other external interest[s] that impair[ ] or might reasonably appear to impair the Senior Official's independence of judgment in the discharge of his or her responsibilities to the University."

c. Under this Operating Principle, faculty must, in advance of certain transactions or as soon as becoming aware, notify their School Dean (or the Dean's designee) of any reportable financial relationship they or members of their family have with an outside entity involved in the transaction. Specifically, faculty must report financial relationships with any outside entity that is known by the faculty to: (a) fund University-sponsored research in which the faculty member participates or proposes to participate; (b) own or have a contractual right to develop or exploit intellectual property or a product or technology that is the subject of research in which the faculty member participates or proposes to participate; (c) compete commercially with an entity that owns or has a contractual right to develop or exploit intellectual property or a product or technology that is the subject of research in which the faculty member participates or proposes to participate; (d) make or propose to make a gift to the University that would support the faculty member's teaching or research activities; (e) furnish products or services to the University through a contractual process in which the faculty member participates in any way; (f) propose to enter a licensing agreement with the University with respect to technology invented by the faculty member; (g) act as a legal or *de facto* agent for any outside entity engaged in any of the above activities. In such cases, approval by the School Dean will be required before the transaction may commence or continue. The Dean's approval may be withheld or conditioned on measures to reduce, manage, or eliminate any financial conflict of interest.

8. <u>Annual reporting of financial interests</u>. Important benefits accrue from requiring that faculty report, for review by disinterested School officials, all outside financial interests and related outside professional activities that may, or may reasonably appear to, influence inappropriately the discharge of their University obligations. Such reporting 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, faculty members shall submit, in the format prescribed by their School, annual reports of their and their family members' outside financial interests, as well as promptly filed updates of material changes in these interests, to their School Dean (or to an individual or committee designated by the Dean), who may require prior approval of material changes in these interests. School Deans (as well as senior officers and administrators of the University) shall file their own annual reports 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. All financial reports 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, or as otherwise authorized by the School's Implementation Plan.

<u>Annotation</u>

a. This policy adopts the growing practice among research universities and academic medical centers to distinguish between "reporting" and "disclosing." "Disclosure" means a release of information about individuals' financial interests related to academic responsibilities to parties *external to* the institutional conflict of interest review and management processes. "Reporting" means the provision by individuals of information about their financial interests related to their academic responsibilities *internally* to institutional officials and bodies designated in their School's Implementation Plan.

b. The definition of financial interests that must be disclosed to federal sponsors will continue to be the province of regulation.* Under current PHS regulations (codified at 42 C.F.R. § 50.603 and 45 C.F.R. § 94.3) and NSF regulations on financial conflicts of interest, the term "significant financial interest" is used to denote an interest that must be reported to and managed by the institution *and* disclosed to the sponsoring federal agency. The definition of "significant financial interest," which first appeared in 1995 in PHS regulations, includes (1) payments from an interested company expected to exceed $10,000 in the ensuing twelve months, and (2) equity in an interested company exceeding either $10,000 in value or a five percent ownership interest. Although these thresholds have since been adopted in many medical school and university conflict of interest policies, the $10,000 and 5% figures have no inherent validity but rather represent political compromises reached through the hard bargaining that is intrinsic to the regulatory process.

* The PHS regulations are currently undergoing review and revision pursuant to an Advance Notice of Proposed Rule Making issued by the National Institutes of Health on May 8, 2009. *See* Federal Register, Vol. 74, pp. 21,610 - 613.

c. This policy provides substantial discretion to the Schools to determine the financial interests and related outside professional activities that a faculty member must report to the School on an *ad hoc* basis and annually, which of these reported interests and activities require institutional management and the detailed specifications of that management, and which require the Dean's prior approval. In their determination of what constitutes a reportable financial interest or related outside professional activity and how such interests and activities should be evaluated and managed to minimize the risks that conflicts 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, the Schools should be cognizant of new insights into the scientific foundations of influence and reciprocity. 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 and determining their *de minimis* reporting thresholds. Above the *de minimis* threshold chosen by a School, faculty members in that School should report all outside financial interests and professional activities that may be deemed in any way related to their University or professional responsibilities. In determining "relatedness," faculty should apply a standard of common sense, and when in doubt, report.

d. 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, Deans are strongly advised to require their faculty members to obtain their prior approval before assuming such responsibilities.

e. Faculty members must be diligent in meeting their reporting obligations under the provisions of this Operating Principle, Operating Principle 7, and their Schools' Implementation Plans. If uncertain about any aspect of these obligations, faculty members should seek guidance from the School official or body designated to manage the review of financial reports.

f. Annual reports 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 reportable 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, and it may include the faculty member's best approximation of the size or value of the interest for the 12 months that follow. Individuals who have no reportable financial interests shall certify to that fact in writing. In addition, annual reports 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.

g. If, after the submission of an annual report, there is a material change in a faculty member's financial interests, the faculty member should update his or her report 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 report expected changes or newly anticipated financial interests before they occur to enable meaningful evaluation by responsible School officials.

h. 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, nor will the OSP (or the SRAs) transmit such a proposal or the OTD sign such an agreement, unless each faculty member participating in the research project certifies on the institutional routing sheet to having filed an accurate and up-to-date annual report.

i. The Schools have discretion to decide the extent to which holders of visiting faculty or teaching appointments shall be subject to reporting or disclosure obligations under this policy. However, the Schools are encouraged to require that (1) visiting faculty whose appointments require them to participate in academic duties within the School for six months or longer report and disclose financial interests that are directly related to their Harvard responsibilities, and (2) regardless of the length of time of their participation in duties at Harvard, visiting faculty comply with Operating Principle 7 and report any outside financial relationships that pertain to transactions that arise during their Harvard service.

9. **<u>Disclosure</u>. To promote the transparency essential to societal trust in the University and its faculty, faculty members receiving financial support for their academic work, or having financial interests in or related to the subject matter of the work as defined in their School's Implementation Plan, are expected to disclose such interests and sources of support in all publications, public reports, communications to the media, and formal presentations, written or oral, concerning that work and to comply with the disclosure requirements of their professional journals and societies. Disclosure of support and financial interests is also expected when faculty members are sought as experts to inform the public on matters of concern and to help shape public policy. None of the above provisions is intended to compromise professional duties of confidentiality or violate confidentiality protections dictated by law or professional codes of conduct.**

Annotation

a. Disclosure is the bedrock of conflict of interest policies within and without academe. In traditional economics, the value of disclosure is understood to inform and enable listeners appropriately to discount the credibility and influence of the speaker's opinion or advice. Recent research in psychology and behavioral economics has demonstrated – unexpectedly – that disclosure can in fact enhance the perceived stature and authority of the discloser, lending his/her advice even greater weight. Given these new scientific insights, one might question the value of disclosure in the first instance. This Operating Principle affirms that the abiding value of disclosure is to make potentially problematic financial interests publicly known and obviate opportunities for corrosive accusations of concealment detrimental not only to the individual but to institutional and sector credibility.

b. Disclosure in no way cures a financial conflict of interest but is an essential step in responding to such conflicts. A comprehensive response may also require elimination, reduction, or credible independent management of the conflicting interest.

c. Faculty members are often sought as experts to inform the public about matters of concern, to help shape public policy, and, more generally, to legitimate knowledge. 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 Operating Principle and disclose financial interests and sources of financial support that could be seen as biasing.

d. Faculty members are expected to comply with this Operating Principle irrespective of, and in addition to, the disclosure requirements of their professional journals and societies.

e. In addition to the disclosures required by this Operating Principle, faculty members may be required to make other disclosures concerning their financial interests as part of a plan for managing conflicts of interest developed and imposed under Operating Principle 10. For example, 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).

f. Disclosure may also be advisable when the content of lectures intended for student audiences includes subject matter in which the lecturer holds a financial interest.

g. A School Dean may determine on academic grounds that disclosure of a financial interest related to a particular academic activity or class of activities is inadvisable.

10. <u>Review and management of financial interests</u>. Each School shall adopt an Implementation Plan establishing procedures to ensure timely review of their faculty's annual and *ad hoc* reports 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 be submitted to the sitting University-wide Committee on Financial Conflicts of Interest for review and approval. Subsequently, changes in School plans shall be reviewed and approved by the standing University Committee on Financial Conflicts of Interest to be appointed by the Provost.

<u>Annotation</u>

a. Each School Dean, or other official or committee designated by the Dean, shall be responsible for reviewing annual and *ad hoc* faculty reports of financial interests and determining whether such interests create conflicts of interest under the University Policy or the School's Implementation Plan. Reviewing officials or committee members who have a conflict of interest in reviewing reported 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 Vice Provost for Research, who may designate an alternate from within or without the School to conduct the review.)

b. 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 and the School's Implementation Plan. 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 where (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.

c. 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.

d. 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.

e. School Deans should be held accountable for effective enforcement of this policy and their own Implementation Plans.

f. Appendix I to this policy contains a Model Financial Conflict of Interest Policy Implementation Plan. The model plan conforms to the requirements of this policy and is offered as guidance to the Schools.

11. **<u>Sanctions</u>. 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 and School Implementation Plans. Knowing failures to file timely annual or *ad hoc* transactional reports of financial interests or updates of material changes of financial interest, willful submission of materially incomplete or inaccurate reports, 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 Vice Provost for Research as appropriate, deem warranted.**

Annotation

a. The University and the Schools should undertake robust programs of education and communication to make all faculty, students, and staff aware of the requirements of the University's Policy on Individual Financial Conflicts of Interest and Schools' Implementation Plans, and that failure to adhere to these requirements affronts academic integrity, invites embarrassment and public censure, and may result in sanctions.

b. Every member of the University faculty should view with utmost seriousness his/her obligation to report outside financial interests fully, accurately, and timely, 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.

c. School Implementation Plans should specify the range and types of sanctions and remedies to be applied under this policy.

12. University Oversight. The Vice Provost for Research, 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 Vice Provost for Research shall provide advice to Deans concerning the interpretation and application of this policy, and should be consulted in all cases where interschool scholarly activity implicates differing plans for implementation of this policy. In addition, Deans should consult with the Vice Provost for Research 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. Each School shall submit for review by the Vice Provost for Research and the Committee 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 Vice Provost for Research shall report annually to the Joint Committee on Inspections on the status of this policy and its implementation. The Vice Provost for Research, 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 annual and *ad hoc* 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, educating faculty and administrators, and otherwise enhancing 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.