HARVARD UNIVERSITY

Introduction to Financial Interests Disclosure Requirements

- Please read each section below.
- Definitions for *italicized* terms can be found by clicking here.

1. OVERVIEW AND BACKGROUND

- The following text highlights the key elements of the Harvard University *Policy on Individual Financial Conflicts of Interest* and the recently published US Department of Health and Human Services (HHS) Rule on the *Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding is Sought* (**the "PHS Rule"**).
- If you are a subrecipient Investigator on an award administered by Harvard, "School" below refers to the Harvard School at which the Harvard Principal Investigator is appointed.
- Each school at Harvard has an Implementation Plan that provides important information that supplements the University policy. You should read the Plan carefully.
- *Frequently Asked Questions* about the University policy are available here and *Frequently Asked Questions* about the PHS Rule are available here.
- If you have additional questions, you should contact a school's designated institutional official (DIO). A list of DIOs is available here.

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

The University and PHS policies share the common goal of protecting the integrity of scholarship and research. Increasingly, faculty engage in extramural activities with industry and other outside constituencies. These activities further Harvard's mission to serve society and act as a powerful catalyst for the advancement of knowledge. At the same time, these activities can give rise to personal financial interests that may be at odds with a faculty member's primary professional responsibility to the University. Accordingly, it is appropriate that the University assist faculty in determining the existence of potential financial conflicts of interests and managing such conflicts when they are found to exist.

2. INTERNAL DISCLOSURE REQUIREMENTS

- You must disclose to your school any significant financial interests (both your own and those of your spouse and any dependent children) in entities that are related to your institutional activities.
- You must internally disclose at least annually and more frequently if you acquire new significant financial interests. PHS investigators are subject to additional disclosure requirements.
- You should familiarize yourself with your school's Implementation Plan, as specific disclosure requirements may differ by school and discipline.

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 school officials and bodies designated in their school's implementation plan.

In previous years, faculty members have been asked to determine whether any of their financial interests may pose a potential conflict with their research, and then disclose them to School officials. The University policy adopts a new disclosure paradigm that puts the responsibility for identifying potential conflicts on the institution and broadens the scope of activities that may be in potential conflict with personal financial interests. Therefore, faculty members are now required to disclose all *significant financial interests* in *related outside entities*.

What to Disclose

The details of what you need to disclose are determined by your school's implementation plan. You should read this plan carefully and familiarize yourself with its disclosure requirements. At a minimum, you must disclose all *significant financial interests* in *related outside entities* - both your own and those of your spouse and dependent children. You need only disclose interests in related outside entities. When in doubt, disclose.

You must disclose:

1. financial compensation, including travel, from consulting, employment, managerial, and fiduciary relationships that, when aggregated over the preceding twelve months, exceed $5,000;
2. equity and other financial interests above $5,000;
3. equity interests of any amount, or entitlement to the same, in a non-publicly traded, for-profit, entity; and
4. intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income related to such rights and interests.

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

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

You may have questions about how these disclosure requirements apply to your specific financial interests. Frequently Asked Questions are available here. Your school's designated institutional official is also available to answer questions - contact information for school officials is available here.

Among the most commonly asked questions are:

- Do I need to disclose royalties from textbooks that I or my spouse have authored?
  - Yes. If these royalties exceeded $5,000 in the last twelve months, you must disclose them internally to your School. You do not need to disclose royalties paid through Harvard.

- Do I need to disclose equity held in a mutual fund or blind trust?
  - No. You do not need to disclose investments or equity holdings that you do not control. And, even when you do control an investment, you need only report it if it is in an entity that is related to your institutional activities.

When to Disclose

You must disclose these interests at least annually. You will be reminded to disclose by your school. If you acquire a *new* significant financial interest that was not previously disclosed, you should disclose the new interest within 30 days. Finally, you must ensure that you have filed a disclosure or any necessary updates prior to: accepting gifts; submitting an application for a sponsored project; or initiating a technology licensing agreement.

3. PUBLIC DISCLOSURE REQUIREMENTS

- Once identified by your school's designated institutional official, conflicts of interest must be managed.
- Public disclosure of such interests is likely to be an essential part of any management plan.
- Additionally, you are required to publicly disclose any financial interest (whether above $5,000 or not) to which you believe reasonable members of an audience would give weight in assessing the opinions, advice, or work you are presenting.

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, 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, in their reasonable judgment, reasonable members of the audience would give weight to those interests in assessing the opinions, advice, or work they are presenting. 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. Faculty members are also expected to comply with the disclosure requirements of their professional journals and societies.

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, the school official 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.

4. ADDITIONAL REQUIREMENTS FOR PHS INVESTIGATORS

- "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 the University policy.
- In general, if you comply with the University policy, you will be in compliance with the PHS regulations. However:
  - You must make certain disclosures about your travel that are not required by the University policy, and;
  - Any financial interests that are determined to be *conflicts* of interest and that relate to your PHS-funded research may be disclosed publicly

Frequently Asked Questions about the regulations that apply to PHS-funded research are published by the National Institutes of Health and are available here.

The University will not submit a proposal for PHS funding unless all individuals identified on the proposal as investigators have filed an up-to-date disclosure of significant financial interests.

The US Department of Health and Human Services (HHS) issued its Final Rule on the *Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors* on August 25, 2011. The Rule implements significant changes to regulations last updated in 1995 that govern the relationships between PHS-funded investigators and industry. Like the University policy, the new PHS Rule requires disclosure by investigators and analysis by the institution of all significant financial interests that are related to an investigator's University activities.

The PHS Rule is broader than the University policy in that it requires disclosures from *investigators* (and not just faculty) and in that it requires the disclosure of all reimbursed and sponsored travel related to University responsibilities, even if such travel does not cross the $5,000 threshold for significant financial interests.

Who is an investigator?

As a Principal Investigator on a proposal for PHS funding or a current PHS-funded award, you are responsible for identifying all individuals on the award who are *investigators* for the purposes of the PHS conflict of interest rule. The term '*investigators*' encompasses more than just the *key personnel*:

An 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 funded by the PHS, which may include, for example, which may include, for example, collaborators or consultants." Included as investigators should be anyone who leads, manages, or makes a substantive contribution to a significant research-related activity (including proposal development, conduct of research procedures, and/or analysis or reporting of results).

Once identified as an investigator, an individual will be required to complete annual financial interest disclosures and required updates as specified in the University *Policy on Financial Conflicts of Interest*. Additionally, all PHS investigators must disclose the occurrence of certain categories of travel.

Disclosing Travel

Beginning August 24, 2012, 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.

Public Disclosure of Identified Conflicts

Any financial interests that are determined to be *conflicts of interest* and that relate to your PHS-funded research may be disclosed publicly, as required by the PHS rule, and before the expenditure of any funds under the PHS-funded research project. In such instances, the following information will be made available on a publicly-accessible website:

- Your name
- Your title and role with respect to the research project
- The name of the entity with which the financial interest is held
- The nature of the significant financial interest
- The approximate dollar value of the significant financial interest

5. THE ROLE OF THE INSTITUTION

- Access to disclosed information is limited: your submitted disclosure will be held in confidence by the official(s) designated by your school's Dean.
- Unless otherwise stipulated by your school or by legal obligations, your disclosed information will be used only to assure compliance with conflict of interest policies and regulations.
- If your school's designated institutional official identifies a conflict arising from your disclosed financial interest, s/he will propose a plan for managing, reducing or eliminating the conflict.
- The University Standing Committee on Financial Conflicts of Interest oversees implementation of the University fCOI Policy

Confidentiality and Security

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

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

Access to Disclosed Information

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

Every school designates one or more individuals to receive and review uploaded financial interest disclosures. No other person, inside the School or outside it, may access information provided by users. Every school establishes its own policy specifying who will have access to disclosures in order to review them. Harvard University Information Technology (HUIT) employees, under strict confidentiality requirements, may have access to personally identifiable information for authorized system maintenance purposes.

Review of Disclosed Information

Once disclosed, your school's designated institutional official (DIO) will review your significant financial interests and your institutional responsibilities. The process for this review will vary by school. Often, the DIO will work with you to determine if a conflict of interest exists.

In all cases, if a conflict of interest is identified, your school's DIO will draft a management plan that outlines the measures required to manage, reduce or eliminate the conflict. In some instances, such management will consist of only limited public disclosure; in other instances, management might extend to divestiture of the conflicting interest.

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.

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.

University Standing Committee on fCOI

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.

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.

The University policy requires that the Provost's office report annually to the Joint Committee on Inspections on the status of the 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 in order to (1) evaluate compliance with the 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.