

Training and Education Information

1. Introduction

a. Purpose

The purpose of this training is to inform you of Harvard University's policies and procedures regarding outside professional activities and financial interests and the federal regulations that underlie them. It also includes information about what outside professional activities and financial interests should be reported, when you are required to report them, and how the University reviews them.

b. University and School Policies

This Outside Activity and Interest Reporting (OAIR) system exists to implement the:

- [Harvard University Policy on Individual Financial Conflicts of Interests for Persons Holding Faculty and Teaching Appointments](#) (fCOI Policy) along with the implementation plans developed by the individual schools under this policy, and
- [Statement on Outside Activities of Holders of Academic Appointments](#) (Outside Activities Statement)

Together, these documents outline the obligations of holders of academic and research appointments at Harvard to disclose their outside professional activities and financial interests to the University.

c. Definitions

A **conflict of interest** exists when your obligations to an outside entity are at odds with your obligations to the University to such an extent that the circumstances create the potential to influence your professional judgment.

A **conflict of commitment** exists when the amount of time and effort you dedicate to outside activities compromises your capacity to fulfill your University obligations.

For further definitions of terms used herein, please refer to the [Definitions and Terms](#).

d. Training Frequency

The system will prompt you to complete this training before using it for the first time, at least once every four years thereafter, and whenever significant updates or changes to the policies governing this system take effect.

2. Discloser Responsibilities

a. Who Must Disclose

The fCOI Policy requires that all faculty members, individuals holding teaching appointments, and at least all individuals who are responsible for the design, conduct or reporting of research projects funded by Public Health Service (PHS) (such as the National Institutes of Health, Centers for Disease Control, and Food and Drug Administration), sponsors that follow PHS requirements, and the National Science Foundation (NSF) disclose their outside professional activities and financial interests at least annually. Certain schools within the University may require additional populations, such as research staff members or anyone listed as an investigator on a current or

pending sponsored award, to report their outside professional activities and financial interests. Further information about how each school defines its disclosure population can be found here: vpr.harvard.edu/OAIR.

b. What to Include in your Disclosure

You are required to include information about “related” outside professional activities and financial interests, or those that could reasonably appear to relate to your University responsibilities, regardless of whether you are compensated. Outside professional activities and financial interests could impact your University responsibilities if they detract from the time and effort you spend on your University responsibilities or may influence or appear to influence the decisions you make in your role at the University. Outside professional activities and financial interests involve entities that are outside of Harvard (foreign or domestic, for-profit or not-for-profit) with which you, your partner/spouse, or your dependent children (“family”) have had a relationship in the last 12 months, except as noted in “What Not to Include in your Disclosure” below. The following are examples of outside professional activities and financial interests that should be included in your disclosure:

Related financial interests, equity holdings, ownership, and fiduciary relationships

- Equity or other ownership interests, including any shares of stock, options, warrants, promises of such, etc., whether the company is privately or publicly held and regardless of whether the equity currently has any value.
- Potential income related to inventorship/authorship on intellectual property (IP) that is licensed to an outside entity (including but not limited to inventions, copyrighted works, and trademarks) regardless of whether royalties have been received.
- Any paid or unpaid fiduciary or management role as an officer, director, or member of a governing board (e.g., board of directors or the equivalent) in a related outside entity.
- Any other financial interests or related compensated activities held by you or your family.

Related outside professional activities

- Professional services or employment, including any:
 - Appointment, affiliation, or employment agreement with any outside entity, foreign or domestic
 - Private consulting or membership on a scientific or other advisory board
 - Teaching a program outside of Harvard
 - Office held in a professional organization
 - Services provided to a non-US government (including testimony)
 - Paid media appearances
 - Expert witness testimony
 - Editorial services
 - Architecture, planning, or design project services
 - Participation in:
 - Fellowship and artists’ residencies (other than under an award through Harvard)
 - Exhibitions, design projects, professional juries (including design juries), or
 - Foreign talent recruitment or development programs
- Conducting research or otherwise being listed on a sponsored award on behalf of a program outside of Harvard

- Prizes, including awards and honoraria
- Speaking engagements and travel support or reimbursements, including travel paid on your behalf by a third party. Note: you need not include speaking engagements for and travel that is reimbursed or sponsored by US federal, state, or local government entities or US-based institutions of higher education and affiliated medical centers. However, speaking engagements for and travel that is reimbursed or sponsored by non-US government agencies and institutions of higher education need to be included.
- You should include any professional activities with outside entities that receive payments on your behalf. For example, if you are part of a practice or foundation, or an organized consulting group that receives payment for your work, the consulting group and the companies that paid you through the consulting group should be listed. Payments from any corporate sponsor that pass through an intermediary should be attributed to the primary sponsor. For example, if a pharmaceutical company hires a public relations firm to arrange seminars in support of the company's product, the payments should be attributed to the pharmaceutical company, not the firm, regardless of which entity's name appears on the check you receive (or anticipate receiving).

If it is unclear whether an outside professional activity or financial interest should be included in your disclosure based on the above criteria, the recommendation is to include it. These reporting requirements are independent of whether your outside professional activities or financial interests present a potential, perceived, or actual conflict of interest or commitment.

Please note that the [Statement on Outside Activities](#) requires additional school-level approvals for professional relationships that are closest to your Harvard obligations, such as teaching or conducting research at an outside entity. These approvals should be obtained prior to initiating such engagements and then disclosed herein as required.

c. What Not to Include in your Disclosure

- Unpaid outside activities performed by your family
- Sponsored awards through Harvard
- Salary or other remuneration paid to you by Harvard if you currently hold a Harvard appointment, other than IP payments
- Speaking engagements for and travel that is reimbursed or sponsored by US federal, state, or local government entities or US-based institutions of higher education and affiliated medical centers. This exclusion only applies domestically. All international speaking engagements and reimbursed or sponsored travel must be disclosed.
- Investments in, or income from, investment vehicles, such as mutual funds or retirement accounts, so long as the investigator does not directly control the investment decisions made in these vehicles

d. When to Disclose

You are required to submit a disclosure on the following schedule:

- an annual basis,
- within 30 days of acquiring a new outside professional activity or financial interest, and
- for research projects as required by certain sponsors and school-level policies.

Each school has adopted a schedule by which annual submissions of outside professional activities and financial interests are due. You will be notified of your annual disclosure period in

advance of the due date. In each case, the disclosure will cover the 12-month period preceding the submission. It is your duty to track new outside professional activities and financial interests and report them in the system in a timely manner. Additionally, you will be notified of your disclosure obligations for research projects that require research-specific disclosures when they are awarded.

e. Record Keeping

It is your responsibility to maintain records to verify that your disclosures are complete and accurate by retaining documents such as payment records, contracts and agreements, travel receipts, etc., for at least three years from the date of submitting your disclosure.

3. Role of the University

In the context of outside professional activities and financial interests, the University's responsibilities are to:

- Obtain and review outside professional activities and financial interest disclosures
- Determine whether real or perceived conflicts of interest or commitment exist and take steps to manage, reduce, or eliminate them
- Ensure that identified conflicts are reported to sponsors as required by their regulations
- Otherwise ensure compliance with sponsor and University policies

a. Disclosure Review

Designated staff at your school will review the information you submit through this system to determine whether conflicts of interest, conflicts of commitment, and other compliance matters exist (see "Examples of Potential Conflicts of Interest" below). Beyond the primary reviewing office in each school, your disclosure or elements thereof will only be shared with University officials and bodies on a need-to-know basis in a specific instance. For details on what school officials will have access to what portions of your disclosure, refer to your school's implementation plan.

b. Management of Potential Conflicts of Interest

If a conflict of interest is identified, designated staff in your school will work with you to manage, reduce, or eliminate the conflict and develop a conflict management plan if needed. Your agreement to the management plan must be documented before sponsored funding related to the financial interest can be released. Once the management plan is in place, you will be responsible for compliance with its terms and conditions. Common elements of a management plan include:

- Targeted disclosure of the nature of the conflicts of interest in publications and presentations, to collaborators and trainees, students in a faculty member's courses, patients, staff, or research participants
- Monitoring of the research activity by independent reviewers
- Disqualification from participation in all or a portion of the activity
- Reduction or divestiture of financial interests
- Severance of relationships that create actual or potential conflicts

c. Sponsor Reporting Requirements

Some sponsors require financial conflicts of interest related to their proposals and awards to be reported to the sponsors themselves. The most specific requirements are for investigators on

PHS projects at award stage (see Section 4), with some private foundations adopting this requirement as well. Other sponsors require formal notifications at proposal stage. Your school will follow the appropriate procedures for reporting conflicts on your behalf as needed.

4. Requirements for PHS and NSF Investigators

This section applies only to faculty and researchers who are identified as “investigators” (see definition below) on proposals or awards from [PHS agencies and private sponsors following PHS rules for conflicts of interest](#), as well as NSF (see [NSF COI policy](#)).

a. PHS and NSF Conflict of Interest Regulations

The US Department of Health and Human Services's [Final Rule on the Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding is Sought](#) outlines the University's obligations regarding oversight of its researchers' financial interests and engagement in outside entities. It prescribes criteria to evaluate the financial interests and outside activities, procedures to implement a compliance program, and a requirement for the University to maintain and enforce a conflict of interest policy. You can find Frequently Asked Questions about these regulations [here](#).

NSF's Conflict of Interest Policy similarly outlines the University's obligation to maintain a conflict of interest policy and determine whether NSF-funded investigators have a conflict of interest related to NSF-funded awards, including the provision of criteria to make this determination. However, under NSF's policy, the University is empowered to manage or eliminate the conflicts internally and only needs to report to NSF if the conflict cannot be managed satisfactorily.

b. Who Is an Investigator

The PHS Final Rule defines an “investigator” as “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, collaborators or consultants”. Similarly, the NSF guidance defines an investigator as “the principal investigator, co-principal investigators, and any other person at the institution who is responsible for the design, conduct, or reporting of research or educational activities funded or proposed for funding by NSF.” The Principal Investigator (PI) on both PHS and NSF proposals or awards is responsible for identifying investigators.

Once identified as an investigator, individuals will be required to complete annual disclosures according to their institutions' schedules, as well as research-specific certifications at the time of award. The University will not submit a proposal for PHS or NSF funding unless all individuals identified as investigators have an up-to-date disclosure on file.

c. Reporting Requirements

The University must report any financial conflicts of interest identified in connection with a PHS-funded project to the funding agency. This report will include basic information about the project, investigator, and financial interest as well as a summary of how the financial interest relates to the PHS-funded research and how the University is managing the conflict in a management plan.

d. fCOI Public Accessibility

If an investigator is Senior or Key Personnel on a PHS-funded project, and it is determined that a financial interest presents a conflict, the University is required to make certain information about the disclosure available to the public. It can be done either by posting the information on a public website or by providing a written response within five business days of a request. The University will only release information to the public as required by the regulations, such as the following:

1. The investigator's name, title, and role on the project
2. The name of the entity in which the financial interest is held
3. The nature of the financial interest (e.g., consulting, equity, travel)
4. The approximate dollar value of the financial interest

e. Retrospective Review

If the University does not identify or manage an fCOI in a timely manner, including because the investigator did not disclose the interest in the timeline required, the University is obligated to complete a retrospective review of the investigator's fCOI related to the PHS-funded research within 120 days of the determination of noncompliance. The purpose of the review is to determine whether the PHS-funded research was biased in the design, conduct, or reporting during the period of noncompliance because of the fCOI.

If, during a Retrospective Review, the University determines that bias may have affected the PHS-funded research, the University will promptly notify PHS and develop a Mitigation Plan designed to eliminate or mitigate the effect of the bias. The University is required to send a Mitigation Report to the relevant PHS agency that includes information about the project and the PI's financial interest, the reason for the retrospective review, and a description of the impact of any bias on the research project.

Please Note: Consistent with the PHS Final Rule, the University requires fCOI training for all investigators on proposals or awards funded by the NSF, PHS, or [other sponsors that follow PHS rules](#) for conflicts of interest. Reading this document satisfies this requirement.

Harvard Kennedy School (HKS) Requirements

HKS is proud of its energetic involvement in the world. To better understand how to solve public problems by improving policy and leadership, we engage directly with policymakers, public leaders, governments, nonprofit organizations, and for-profit businesses whose activities influence those problems. However, we recognize that such engagement can raise questions about perceived and potential conflicts of interest. Therefore, in addition to the University policy's internal reporting requirements for potential financial conflicts of interest, HKS also requires *public disclosure* of outside professional activities.

Both the internal and public disclosure requirements at HKS are designed to promote transparent engagement with any government, non-profit, civil society, commercial, or other organization that has a financial, ideological, or political interest in the academic activities of our faculty members, where that engagement may influence, or may reasonably appear to an outside observer to influence, the discharge of teaching, research, or other University-related responsibilities.

The HKS public website provides the *Outside Professional Activities* tab for disclosure of these activities as part of each faculty member's HKS profile page. The University's Outside Activities and Interests Reporting system (OAIR) will provide a direct feed of a small number of data fields from each faculty

member's most recent internal disclosure to their profile page for the purposes of public disclosure. This will not require any additional effort by the reporter.

The *Outside Professional Activities* tab appears next to the *Sponsored Projects* tab (for all sponsored principal investigators), which displays key information about sponsored awards (grants and contracts) received by the faculty member and administered at HKS in the past two calendar years. Together, these public disclosures allow for greater transparency and a more complete picture of individual faculty activities in these key dimensions.

Harvard Medical School (HMS) Requirements

There are additional policy requirements for Harvard Medical School faculty:

- Faculty of Medicine Policy on Financial Conflicts of Interest in Sponsored Research: https://ari.hms.harvard.edu/sites/g/files/mcu761/files/phs_policy_2012_sponsored_research_10.27.2016.pdf
- Faculty of Medicine Policy on Conflicts of Interest and Commitment: <https://ari.hms.harvard.edu/outside-activities/faculty-medicine/faculty-medicine-policy-conflicts-interest-commitment>

The integrity of Faculty of Medicine investigators as they pursue their clinical, research and teaching missions is of paramount importance. While Harvard Medical School believes that collaborations with industry are critical to achieving its academic mission, it remains fundamentally important that interactions between Faculty of Medicine investigators and industry be transparent and governed by a policy that further codifies and enforces our high standards.

The Faculty of Medicine seeks to facilitate responsible relationships between industry and faculty who conduct research. There are certain activities and relationships, however, that are presumed to be prohibited and others that are prohibited unless a specific exception is applicable in accordance with this policy. Laid out below are rules with which faculty are required to comply.

An Investigator is presumed to be prohibited from participating in certain research if the Investigator has a financial interest in a company that is providing sponsored research support for the research or has a technology that is being studied as part of the research.

The Clinical Research Rule

Under this rule, an Investigator's participation in clinical research will receive extra scrutiny and may be restricted from participating in the research if the Investigator earns income from or owns equity in a company whose technology is being investigated or serve in a fiduciary role of the company or organization whose technology is being investigated.

Please review the policy at the following link:

<https://ari.hms.harvard.edu/sites/g/files/mcu761/files/assets/HMS%20COI%20and%20Commitment%20Policy%20November%202020.pdf>

The Research Support Rule

Under this rule, an Investigator who participates in research will receive extra scrutiny and may be restricted from participating in the research if the Investigator has an equity financial interest in a business that would like to provide sponsored research support for the research. An Investigator

similarly cannot serve in a fiduciary role and receive sponsored research support from that same company.

Please review the policy at the following link:

<https://ari.hms.harvard.edu/sites/g/files/mcu761/files/assets/HMS%20COI%20and%20Commitment%20Policy%20November%202020.pdf>

The Dual-Career Family Exception

If an Investigator would be in violation of either the Clinical Research Rule or the Basic Research Rule solely by virtue of the career pursuits of the Investigator's spouse or domestic partner, the Investigator may petition the Faculty of Medicine Standing Committee on Conflicts of Interest for an exception.

The Executive Position Prohibition

Individuals who hold a faculty appointment at Harvard Medical School should be aware that full-time faculty may not hold an executive position in a for-profit company or organization engaged in commercial or research activities of a biomedical nature.

Harvard Graduate School of Education (HGSE) Requirements

For HGSE, who discloses should be *"The fCOI Policy and the Outside Activities Statement require that all faculty members (0.5 FTE or greater) and at least all individuals who are responsible for the design, conduct or reporting of research projects funded by Public Health Service (PHS) (such as the National Institutes of Health, Centers for Disease Control, and Food and Drug Administration), sponsors that follow PHS requirements, and the National Science Foundation (NSF) disclose their outside activities and financial interests at least annually."*

What to Disclose:

- For HGSE, disclose all media appearances, paid and unpaid.
- For HGSE, editorial services can include being the editor on a journal or paid for editorial services
- For HGSE, disclose all speaking engagements, including speaking engagements with non-US government agencies (such as hospitals) and institutions of higher education.
- For HGSE, for "prizes and awards" include only paid awards and honoraria and put unpaid prizes and awards in your Annual Faculty Report.