

Faculty of Arts and Sciences (FAS) and John A. Paulson School of
Engineering and Applied Sciences (SEAS)

Policy

Financial Conflicts of
Interest Disclosures

Policy Title:	Policy on Financial Conflicts of Interests Disclosures
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I. INTRODUCTION

The Faculty of Arts and Sciences (FAS) and John A. Paulson School of Engineering and Applied Sciences (SEAS) Policy on Financial Conflicts of Interest (fCOI) Disclosures outlines the detailed FAS and SEAS fCOI disclosure reporting, review, and determination procedures as required by the [University Policy on Individual Financial Conflicts of Interest for Persons Holding Faculty and Teaching Appointments](#)¹ and the [University Procedures for the Implementation of the U.S. Public Health Service Final Rule on the Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought](#). The FAS and SEAS designated institutional official (DIO) appointed by the FAS Dean will bear primary responsibility for implementation of the Policy in accordance with guidelines developed and approved by the Committee on Research Policy (CRP).

II. APPLICABILITY

The Policy on Financial Conflicts of Interest (fCOI) Disclosures applies to all holders of faculty or teaching appointments, individuals holding a $\geq 50\%$ full-time-effort (FTE) in a non-primary faculty appointment or non-faculty academic appointment primarily in the FAS or SEAS², as well as any *Investigator* applying for

¹ Approved by the President and Fellows of Harvard College on May 26, 2010 and incorporating amendments as approved by the President and Fellows on May 23, 2012.

² When the FTE in the FAS or SEAS appointment is less than 50 percent for senior non-ladder or non-ladder faculty, the individual is exempt from required disclosure unless they serve as an *Investigator* applying for or receiving funding from the PHS or NSF. If the individual's FTE in the FAS or SEAS appointment becomes greater than or equal to 50 percent, he or she should submit his or her financial disclosure.

or receiving funding from the U.S. Public Health Service (PHS) (including the National Institutes of Health and the Centers for Disease Control and Prevention), sponsors adopting the PHS regulations³, or the National Science Foundation (NSF). As stated in the University Policy, there may be instances in which cross-faculty and inter-school activities implicate differing school implementation plans, or instances in which a faculty member may be subject to two plans by virtue of a joint appointment. The DIO will consult with the other school with a general goal of selecting *one* implementation plan with which individuals involved must comply. Additionally, schools may consult with the Provost's Office and/or the University Standing Committee on Financial Conflicts of Interest for guidance in complex matters of this type.

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³ Sponsors adopting the PHS regulations include the American Heart Association, American Cancer Society, Arthritis Foundation, Susan G. Komen Foundation, and the Alliance for Lupus Research.

IV. DEFINITIONS

Designated Institutional Official

The FAS and SEAS “Designated Institutional Official” (DIO) appointed by the FAS and SEAS Deans bears primary responsibility for implementation of the policy. The DIO may be assisted by other School officials, the faculty-led Committee on Research Policy, or the FAS or SEAS Deans as needed.

Disclosing Member

The “Disclosing Member” includes an individual holding a primary faculty appointment in FAS or SEAS or an individual holding a $\geq 50\%$ full-time-effort (FTE) non-primary faculty appointment or non-faculty academic appointment primarily in FAS or SEAS⁴. In addition, any *Investigator* applying for or receiving funding from the U.S. Public Health Service (PHS) (including the National Institutes of Health and the Centers for Disease Control and Prevention), sponsors adopting the PHS regulations, or the National Science Foundation (NSF).

Institutional Responsibilities

“Institutional responsibilities” means an individual’s professional responsibilities on behalf of FAS or SEAS. Such responsibilities include, but are not limited to: research, research consultation, teaching, professional practice, institutional committee memberships, and service on committees or panels.

Investigator⁵

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

Related Outside Entity

“Related outside entity” means an entity that may, or may reasonably appear to an outside observer to, relate to a Disclosing Member’s teaching, research, or other University-related responsibilities. In determining relatedness, the faculty member should apply a standard of common sense, and when in doubt, disclose. Examples of such entities include those:

- i. whose products, services, or activities are related to the areas of the Disclosing Member’s teaching or research;

⁴ When the FTE in the FAS or SEAS appointment is less than 50 percent for senior non-ladder or non-ladder faculty, the individual is exempt from required disclosure unless they serve as an *Investigator* applying for or receiving funding from the PHS or NSF. If the individual’s FTE in the FAS or SEAS appointment becomes greater than or equal to 50 percent, he or she should submit his or her financial disclosure.

⁵ “Investigator” for purposes of compliance with the conflict of interest regulations of the Public Health Service is broader than the class of faculty and holders of teaching appointments under this policy. For PHS purposes, “investigator” is “the Project Director/Principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, including persons who are subgrantees, contractors, collaborators, or consultants.” Therefore, in order to comply with PHS regulations, it may be necessary, in specific grants, for post-doctoral candidates, fellows and even graduate students, to complete internal disclosures under this policy. See 42 C.F.R. 50.602 (definition of “investigator”).

- ii. that fund research in which the Disclosing Member participates or proposes to participate;
- iii. that own or have rights to develop intellectual property that is the subject of research in which the Disclosing Member participates;
- iv. that make or propose to make a gift to the University that would support the Disclosing Member's teaching or research activities;
- v. that furnish products or services to the University through a contractual process in which the Disclosing Member participates in any way;
- vi. that have or propose to enter a licensing agreement with the University with respect to technology invented by the Disclosing Member;
- vii. that act as a legal or *de facto* agent for any outside entity engaged in any of the above activities (if the original source of remuneration or equity interest paid through a third party is known by the Disclosing Member, it should be disclosed).

Significant Financial Interest

"Significant Financial Interest" (SFI) includes, but is not limited to, (1) financial compensation from consulting, employment, managerial, and fiduciary relationships above \$5,000; (2) equity and other financial interests above \$5,000; and (3) equity interests of any amount, or entitlement to the same, in a non-publicly traded, for-profit, entity. In all cases, the SFI will be calculated per entity reported in the preceding twelve month period and will be calculated on the aggregation of the sum total of the Disclosing Member, his or her spouse and dependent children.

V. DISCLOSURE REQUIREMENTS

i. Designated Institutional Official

A Designated Institutional Official (DIO) appointed by the FAS and SEAS Deans will bear primary responsibility for implementation of this policy. The DIO will review the internal financial interest disclosures submitted annually by FAS and SEAS faculty and holders of teaching appointments as well as disclosures submitted by *Investigators* on PHS, sponsors following PHS regulations, and NSF proposals and awards. Additionally, the DIO may need to review financial interest disclosures submitted by non-FAS and non-SEAS individuals who are designated as *Investigators* on FAS- or SEAS-led proposals and awards. Likewise, the DIO may need to consult with a non-FAS or non-SEAS School's DIO if a FAS or SEAS faculty or holder of teaching appointment is designated as an *Investigator* on a non-FAS- or SEAS-led proposal or award.

The DIO serves in an administrative and advisory capacity only and is responsible for the initial review of SFI and identification and management of potential fCOI situations with the disclosing member. The DIO advises and provides support to the CRP, Chair of the CRP, and ad hoc faculty committees formed by the Chair of the CRP if the fCOI cannot be managed at the DIO level or if a mutual agreement for fCOI management cannot be met between the DIO and Disclosing Member.

ii. Financial Interest Disclosure

An individual holding a primary faculty appointment in FAS or SEAS or an individual holding a $\geq 50\%$ full-time-effort (FTE) non-primary faculty appointment or non-faculty academic appointment

primarily in FAS or SEAS must submit an internal, confidential disclosure of their and their family members' *significant financial interests* in the preceding twelve months in any *related outside entity* using the online [Financial Interest Disclosure](#) application. In addition, any *Investigator* applying for or receiving funding from the U.S. Public Health Service (PHS) (including the National Institutes of Health and the Centers for Disease Control and Prevention), sponsors adopting the PHS regulations, or the National Science Foundation (NSF) must submit an internal, confidential disclosure of their and their family members' *significant financial interests* in the preceding twelve months in any *related outside entity* using the online [Financial Interest Disclosure](#) application.

Any Faculty and *Investigator* applying for or receiving funding from the PHS, sponsors adopting the PHS regulations, or the National Science Foundation (NSF) must update disclosed information (*e.g.*, a change in value of a previously disclosed interest) at least annually, within 30 days of the discovery or acquisition of a new significant financial interest, and prior to the following actions:

- Accepting gifts
- Submitting an application for a sponsored project
- Receiving funding for a sponsored project
- Initiating a technology licensing agreement

iii. **PHS Travel Disclosure**

Any *Investigator* submitting a proposal to or receiving funding from the PHS must disclose to the DIO the occurrence of any reimbursed or sponsored travel (*i.e.*, that which is paid by an outside entity directly to or on behalf of the *Investigator* so that the exact monetary value may not be readily available) that falls within the following guidelines:

- Travel must be related to institutional responsibilities.
- Travel is not being reimbursed or sponsored by a federal, state, or local government agency, or domestic or U.S.-based 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.
- *Investigator* has an aggregate of significant financial interests and travel reimbursements that exceed \$5,000 in the previous twelve months from a single entity. As an example, \$4500 in non-travel significant financial interests and \$1000 in travel reimbursements would exceed \$5,000 when aggregated from a single entity, and, therefore, would need to be disclosed.

Travel information must be disclosed within 30 days upon completion of the travel using the online [Financial Interest Disclosure](#) application and must include the following information:

- The purpose of the trip
- The identity of the sponsor/organizer of the trip
- The destination of the trip
- The duration of the trip

iv. **Disclosure Examples**

Examples of financial interests that should be included in disclosure⁶:

- a. Salary or any other remuneration (including consulting fees, honoraria, paid authorship, or other compensation) received from an entity⁷ other than Harvard University (see exclusions below);
- b. Stocks, stock options or other ownership interest in a publicly traded entity;
- c. Any equity interest (e.g., stocks, stock options, or other ownership interest) in a non-publicly traded entity, regardless of dollar amount;
- d. Intellectual property rights and interest (e.g., patents), upon receipt of income related to such rights and interests unless paid by Harvard University;
- e. Holdings in a targeted mutual fund or hedge fund⁸;
- f. Income from books and other publications, whether hard copy or electronic, in excess of \$5,000 for a single work.

Examples of financial interests that may be excluded from disclosure:

- a. Salary or other remuneration, including royalty payments, paid by Harvard University;
- b. Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, a domestic or U.S.-based 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;
- c. Income from service on an advisory committee or review panel for 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;
- d. An equity interest in a publicly-traded entity that, when aggregated for the Disclosing Member and the Disclosing Member's spouse and dependent children, does not exceed \$5,000 in value as determined through reference to public prices or other reasonable measures of fair market value;
- e. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Disclosing Member does not directly control the investment decisions made in these vehicles;
- f. Stocks in large publically traded companies that have equipment in the Disclosing Member's laboratory, unless the stocks were received in compensation for consulting, advisory, or promotional services.

VI. DISCLOSURE REVIEW AND MANAGEMENT

The DIO will bear primary responsibility for the SFI review and management process in accordance with the [Flowchart of Authority for FAS and SEAS Management of Financial Conflicts of Interest](#).

⁶ Received from an entity in the twelve months preceding the disclosure and the value of any remuneration or equity interest in the entity as of the date of disclosure, when aggregated for the investigator and spouse and dependent children, exceeds \$5,000.

⁷ If the original source of the remuneration is paid through a third-party and that source is known, then it should be disclosed.

⁸ Disclosure of specific asset holdings would not be required if such disclosure is prohibited by a non-disclosure agreement.

i. Primary Review (DIO)

The DIO will ascertain whether the disclosed SFI represents a potential financial conflict of interest based on the following criteria:

- Relatedness Standard – An *Investigator’s* SFI is related to proposed research when the DIO reasonably determines that the SFI could be affected by the proposed research or is in an entity whose financial interest could be affected by the proposed research.
- fCOI Standard - An fCOI exists if the DIO reasonably determines that the SFI related to the proposed research could directly and significantly affect the design, conduct or reporting of the proposed research.

The initial review is performed by the DIO who, in situations in which more information is needed, will consult with the Disclosing Member. If the DIO and the Disclosing Member agree that a potential fCOI exists, they will work jointly to implement preventative measures, or develop a management plan, to manage, reduce or eliminate the conflict of interest.

ii. Secondary Review (CRP)

In situations in which the DIO and Disclosing Member cannot agree whether a potential conflict exists or cannot agree on preventative measures to address the potential conflict, the DIO will consult with the CRP. The CRP Chair or other faculty members of the CRP will discuss the situation with the Disclosing Member and try to develop a resolution. If necessary, the CRP Chair, in consultation with the full CRP, has the option to appoint and seek advice from an ad hoc faculty committee with expertise in the programmatic area related to the potential fCOI. The ad hoc committee will make recommendations to the CRP, and the CRP will develop and vote on recommendations based on a majority vote. The CRP will work with the Disclosing Member to implement the recommendations and resolve the potential conflict.

iii. Tertiary Review (University Standing Committee on Financial Conflicts of Interest)

In situations where the CRP and the disclosing member cannot reach an agreement, the disclosing member may appeal the decision of the CRP to the University Standing Committee on Financial Conflicts of Interest. The University Standing Committee on Financial Conflicts of Interest will advise the CRP, and the CRP will present to the Disclosing Member the CRP’s final recommendation to resolve the potential conflict by majority vote.

iv. Final Review (FAS Dean)

If a mutual agreement cannot be met using the previous options in the review process, the Disclosing Member may request the matter be decided by the FAS or SEAS Dean. The decision of the Dean will be final and binding.

VII. MANAGEMENT OF IDENTIFIED FINANCIAL CONFLICTS OF INTEREST

i. Management Techniques

For any identified fCOI, the DIO will take appropriate action to manage the conflict in order to reduce the potential for it to compromise the safety or validity of the research consistent with the requirements of 42 CFR 50.605(a). Research in which an *Investigator* is found to have a fCOI will not be permitted to proceed until a management plan is developed and implemented in accordance with the [Flowchart of Authority](#).

ii. Compliance with Management Plans

Investigators have an on-going obligation to adhere to an imposed management plan and failure to do so may be grounds for sanctions under this policy. FAS and SEAS will monitor *Investigator* compliance with an imposed management plan on an ongoing basis until the completion of the sponsored research project. The CRP, ad hoc faculty committee, University Standing Committee on Financial Conflicts of Interest, and FAS or SEAS Dean may assist in providing a resolution as shown in the [Flowchart of Authority](#).

VIII. REQUIREMENTS FOR REPORTING

i. Sponsor Reporting

The Office of the Vice Provost for Research (OVPR) will send initial, annual and revised fCOI reports to the PHS and NSF consistent with the requirements of 42 CFR 50.604(h) and 42 CFR 50.605(b). To facilitate this reporting, the DIO shall submit to the OVPR's Research Data Compliance and Conflict of Interest Officer information about the fCOI, including all elements of information required by the PHS Rule at 42 CFR 50.604(h) and 42 CFR 50.605(b) at the following times:

- At least 10 days before funds are allowed to be expended on an FAS- or SEAS-managed project
- Within 45 days of identification for an *Investigator* who is newly participating on the FAS- or SEAS-managed project
- Within 45 days for new, or newly identified, fCOIs for existing *Investigator(s)* on the FAS- or SEAS-managed project
- At least annually during the award period
- Following a retrospective review to update a previously submitted report, if appropriate

ii. Annual University Reporting

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

IX. PUBLIC ACCESSIBILITY FOR PHS AWARDS

Unless and until the University establishes a mechanism of making such information available through a publicly accessible website, the Office of the Vice Provost for Research will, upon receipt of a complete written request for information in accordance with the process and requirements outlined on the Office of the Vice Provost for Research [Online Request for Information About Identified PHS COIs](#), provide a written response within five (5) business days regarding any SFI disclosed and still held by the Senior/Key Personnel that has been determined to relate to the PHS-funded research and constitute an fCOI on an FAS- or SEAS-managed PHS award.

In order for the OVPR to make such information available, the DIO will provide information about the fCOI consistent with 42 CFR 50.605(a)(5)(ii) to the OVPR's Research Data Compliance and Conflict of Interest Officer by email within 45 days of the identification of a new fCOI, or sooner if a complete written request for such information is received within the 45-day period.

X. RETROSPECTIVE REVIEW, IDENTIFICATION OF BIAS, AND MITIGATION REPORTING FOR PHS AWARDS

i. Retrospective Review

In the event of failure to meet applicable regulations or policy requirements, including failure by the *Investigator* to disclose timely an SFI that is determined to constitute an fCOI; FAS' or SEAS's failure to review or manage such an fCOI; or *Investigator* failure to comply with an fCOI management plan, the DIO shall, within 120 days of its determination of noncompliance, coordinate a retrospective review of the *Investigator's* activities and the PHS-funded project to determine any bias in the design, conduct or reporting of research during the time period of the noncompliance.

When the *Investigator* submits a SFI that constitutes an fCOI requiring a retrospective review, the DIO would consult with the CRP in accordance with Section V of this policy. Alternatively, if it is determined that there is a potential for misconduct in the *Investigator's* activities during the time period of the noncompliance, the DIO, in coordination with the CRP, would forward the allegation to the attention of the chair of the FAS Standing Committee on Professional Conduct as outlined in the [FAS Procedures for Responding to Allegations of Misconduct in Research](#). The DIO will document the retrospective review in accordance with applicable policies, procedures, and regulations.

ii. Mitigation

If bias in the design, conduct or reporting of research is found during the retrospective review, the DIO will immediately notify the Office of the Vice Provost for Research, who will notify the relevant awarding agency promptly. If applicable, the DIO will develop and implement a mitigation plan, submit any required mitigation report to the Office of the Vice Provost for Research, who will then forward it to the funding agency. The report will include at least the elements documented in the

retrospective review, a description of the impact of the bias on the research project, and FAS' or SEAS' plan of action or actions taken to eliminate or mitigate the effect of the bias. Any fCOI report submitted to the awarding agency with respect to such research will be updated as necessary in light of the results of the retrospective review.

XI. SUBRECIPIENTS

When proposed research is to be carried out through a subrecipient, FAS or SEAS will incorporate as part of a written agreement with the subrecipient, provisions that establish whether the University policy, or that of the subrecipient, will apply to the subrecipient's *Investigators*, as well as the time frames within which the subrecipient must provide any information necessary to ensure that the DIO is able to meet any reporting obligations to the sponsor.

XII. RECORD RETENTION

All financial disclosures will be maintained in a secure format, held in confidence, and released only to the DIO and those institutional officials and bodies with a need to know. Disclosed information will be used (a) to assure compliance with conflict of interest policies and regulations; (b) to comply with subpoenas and other legal obligations. The DIO will retain documentation related to its fCOI review and management process to the extent required by law and any other applicable University, FAS, and SEAS record retention policies.

XIII. SANCTIONS

Faculty members who do not comply with the University policy to report annually their related significant financial interest will, at the FAS or SEAS Dean's discretion, have their reappointment and salary increase delayed. For faculty members and *Investigators* who fail to comply with the PHS regulations, their research proposals will not be submitted by the University to PHS for consideration.

XIV. APPENDIX A

[Flowchart of Authority for FAS and SEAS Management of Financial Conflicts of Interest](#)

XV. UPDATE LOG

May 23, 2012	Original University policy released
May 15, 2013	FAS policy and implementation plan to reflect University policy and implementation plan released
April 28, 2014	Updated to include exclusions to the required participants in "Disclosing Member" definition (Section IV) and Disclosure Requirements (Section V(ii)); clarification of adherence to Flowchart of Authority in Section VII.
October 22, 2015	Updated to add SEAS to plan