

Harvard University – Office of the Vice Provost for Research
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** (42 CFR Part 50)

Updated: August 23, 2012

A. Purpose

Each School has adopted an Implementation Plan pursuant to the University's [Policy on Individual Financial Conflicts of Interest for Persons Holding Faculty or Teaching Appointments](#) ("The University policy"). As required by the University policy, each School has committed to comply with all state and federal requirements applicable to conflicts of interest.

This document provides procedures specific to 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](#) (42 CFR Part 50) and supplements the University policy. As noted in the "Scope" section, below, Harvard will apply the PHS Rule, in part, to additional named sponsors. Schools may adopt the procedures described herein by reference or may adopt separate procedures or policy to reflect School-specific administrative procedures in such a way as to effect more, but not less, stringent requirements.

B. Scope

These procedures apply to research proposed for funding or funded by the U.S. Public Health Service, U.S. National Science Foundation, the American Heart Association, the American Cancer Society, the Arthritis Foundation, the Susan G. Komen Foundation, the Alliance for Lupus Research and any other entity that applies 42 CFR Part 50.¹

C. Definitions

The definitions of words appearing in **bold** are found in the definitions section of the [University policy](#).

D. Procedures

I. Training Requirements

i. Informing Investigators of the Institution's COI Policy and Federal Regulation

The University's Grants Management Application Suite (GMAS) will send a notification to all individuals identified as **investigators**, notifying them of their obligations under the University policy and PHS Rule.

¹ All investigators, regardless of sponsor, are expected to comply with all state and federal requirements applicable to financial interests in research or other academic activities and with the terms and conditions of any sponsored research contract or grant. Individuals with faculty or teaching appointments also must comply with the University's [Policy on Individual Financial Conflicts of Interest for Persons Holding Faculty or Teaching Appointments](#). Only investigators applying for or receiving funding from the PHS are expected to comply with the requirements of the PHS Rule to disclose sponsored or reimbursed travel.



The application will generate this email every time an individual is named as an **investigator** on a project.

ii. Requiring Investigators to Complete Training

Once notified of their obligation to comply with the University policy and PHS Rule, GMAS will direct **investigators** to the University's Financial Conflict of Interest online disclosure system ("fCOI IT system" – fcoi.harvard.edu). This system includes a training screen that **investigators** must complete and certify to having read before filing a disclosure and at least every four years. If an **investigator** has a disclosure on file in the online system, it may be assumed that s/he has completed training. Schools not using the fCOI IT system must ensure that **investigators** have been trained in person or via an online tool other than the fCOI IT system consistent with the requirements of the PHS Rule.

If an **investigator** on a PHS award is found to be not in compliance with the University policy, the PHS Rule, or a management plan, the School must ensure that the **investigator** completes training immediately after such non-compliance is determined. Additionally, an **investigator** must complete the training immediately if these procedures or the University policy are revised in such a way as to affect the requirements of **investigators** or if the **investigator** is new to the University.

II. Disclosure, Review, and Monitoring Requirements

i. Designated Institutional Official

School Implementation Plans must designate an individual to serve as the School's Designated Institutional Official (DIO). In addition to responsibilities under the University policy, the DIO will:

- Solicit and review disclosures of **significant financial interests** (SFIs)
- Review all **investigator** SFI disclosures prior to the expenditure of funds on any project awarded by the sponsors listed in Section B
- Determine if any SFIs relate to research funded by the sponsors listed in Section B
- Determine if a **financial conflict of interest** (fCOI) exists
- Develop and implement management plans as needed to manage fCOIs

ii. Disclosure

All **investigators** must submit, in the form prescribed by their School, an internal confidential disclosure of their and their **family members' significant financial interests** in the preceding twelve months in any **related outside entity**. **Investigators** must update disclosed information at least annually and:

- Within 30 days of the discovery of a new **significant financial interest**; and
- Prior to: accepting gifts, submitting an application for a sponsored project, or initiating a technology licensing agreement.

School Implementation Plans should specify the format for **investigator** disclosures. Schools are encouraged to use the fCOI IT system to collect disclosures and the GMAS system to monitor compliance with disclosure requirements at the proposal and award stage of a sponsored project. If not using these systems, Schools must have in place another system that meets the requirements of the University policy and the PHS Rule.



iii. Review of Disclosures

a. Prior to expenditure of any funds under an award, the DIO must reasonably determine whether any SFI disclosed by an **investigator** is related to the proposed research; if so, whether it can reasonably be determined that the interest constitutes a **financial conflict of interest** (fCOI); and if an fCOI is determined to exist, how the fCOI will be managed consistent with the requirements of 42 CFR 50.605(a).

b. To the extent a new SFI is disclosed to a School in the course of an on-going sponsored research project (i.e., an **investigator** who is new to participating in the research discloses an SFI or an existing **investigator** discloses a new SFI), or the School identifies an SFI that was not previously reviewed in a timely manner by the School, the School shall, within 60 days from the date of the disclosure: (i) determine if the SFI relates to the **investigator's** research; (ii) if it relates, determine if it qualifies as an fCOI; and (iii) if it is an fCOI, implement, on at least an interim basis, a management plan that specifies the actions that have been, and will be, taken to manage such fCOI. The School may, depending on the circumstances of the SFI, conclude that additional interim measures are necessary with regard to the **investigator's** participation in the research between the date of disclosure or identification and the completion of the School's review (including, where warranted, a retrospective review as discussed below).

c. Schools shall establish a process to take such actions as necessary to manage fCOIs, including any financial conflicts of a subrecipient **investigator**, if applicable, and monitor **investigator** compliance with management plans until completion of the sponsored project.

iv. Determining Relatedness

a. *Relatedness Standard:* An **investigator's** SFI is related to proposed research when the School 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.

b. *fCOI Standard:* An fCOI exists if the School 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. Schools may adopt a more stringent, but not less stringent, standard when deemed necessary.

v. Management Techniques

a. For any identified fCOI, the School 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 an fCOI will not be permitted to proceed until a management plan is developed and implemented.



b. 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 School Implementation Plans. Schools must monitor **investigator** compliance with an imposed management plan on an ongoing basis until the completion of the sponsored research project.

III. Requirements for Reporting fCOIs to the Sponsor

The reporting requirements described below will extend only to research funded by the US Public Health Service and the US National Science Foundation.

The Harvard Medical School (HMS) and Harvard School of Public Health (HSPH) maintain direct contact with outside sponsors. These Schools shall therefore establish their own processes to 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).

If requested by a School, 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 at each School (with the exception of HMS and HSPH) 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 the School proposes allowing funds to be expended on a project
- Within 45 days of identification for an **investigator** who is newly participating the project
- Within 45 days for new, or newly identified, fCOIs for existing **investigators**
- At least annually (at least ten days before the School is required to submit the annual progress report, or multi-year progress report, as applicable, or at time of extension)
- Following a retrospective review to update a previously submitted report, if appropriate

IV. Public Accessibility

For PHS-funded Research only, Schools must ensure public accessibility of information concerning the fCOIs held by Senior/Key Personnel pursuant to 42 CFR 50.605(a).

i. Harvard Medical School (HMS): Unless and until HMS establishes a mechanism of making such information available through a publicly accessible website, HMS will, upon receipt of a complete written request for information in accordance with the process and requirements outlined at <http://hms.harvard.edu/content/integrity-academic-medicine>, 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.

ii. Other Harvard Schools: Unless and until Harvard 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 at <http://vpr.harvard.edu/content/request-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 at any School other than HMS.

In order for the OVPR to make such information available, the School DIO must 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.

V. PHS Awards Only: Retrospective Review, Identification of Bias and Mitigation Reporting.

- a. *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; a School's failure to review or manage such an fCOI; or **investigator** failure to comply with an fCOI management plan, the School shall, within 120 days of its determination of noncompliance, complete 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. The School will document the retrospective review in accordance with its policies and procedures and applicable regulations.
- b. *Mitigation:* If bias in the design, conduct or reporting of research is found during the retrospective review, the School (or the Office of the Vice Provost for Research) will notify the relevant awarding agency promptly and, if applicable, develop and implement a mitigation plan, submit any required mitigation report to the funding agency, which will include at least the elements documented in the retrospective review and a description of the impact of the bias on the research project and the School's 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.
- c. *Disclosure for PHS-Funded Drug/Device Research:* In any case in which the Department of Health and Human Services (HHS) determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an **investigator** with an fCOI that was not managed or reported by a School, the **investigator** will be required to disclose the fCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

VI. Subrecipients

When proposed research is to be carried out through a subrecipient, the School 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 School is able to meet any reporting obligations to the sponsor.

VII. Maintenance of Records



Aside from the required disclosures to sponsors and the required provision of certain public information relating to FCOIs and their management, the University policy requires that all financial disclosures shall be maintained in a secure format, held in confidence, and released only to those institutional officials and bodies with a need to know, as authorized by each School's Implementation Plan.² Additionally, all documentation related to the review and response to such disclosures and all actions under the University Policy and these Procedures or retrospective review, if applicable, shall be retained to the extent required by law and any other applicable University record retention policies.

School Implementation Plans should provide guidance for the retention of disclosures and related records that is consistent with [Harvard University's General Records Schedule](#).

VIII. Sanctions

As required by the University policy, School Implementation Plans shall provide for appropriate sanctions and remediation for willful failures by faculty members to comply with the University Policy on Individual Financial Conflicts of Interest, school Implementation Plans, and applicable laws and regulations. These sanctions should extend to any individual identified as an **investigator** on research funded by one of the sponsors listed in Section B.

² There may be circumstances in which the University, in order to comply with judicial subpoenas or government agency demands, may be compelled to make an external disclosure of information relating to conflicts of interest; in such cases, in order to prepare responses to such demands, limited disclosure to the Office of General Counsel and University administration may also be required.

