Implementation Guidance

PLAN FOR IMPLEMENTING "HARVARD UNIVERSITY POLICY ON INDIVIDUALFINANCIAL CONFLICTS OF INTEREST FOR PERSONS HOLDING FACULTY AND TEACHING APPOINTMENTS"

Introduction and Background

This plan implements the Harvard University Policy on Individual Financial Conflicts of Interest for Persons Holding Faculty and Teaching Appointments (the University FCOI Policy) for Harvard Medical School (HMS) and Harvard School of Dental Medicine (HSDM). This introduction will briefly explain the key reasons underlying the University FCOI Policy and how it operates in conjunction with the HMS/HSDM-specific policies: the Faculty of Medicine Policy on Conflicts of Interest and Commitment and the HMS/HSDM Policy on Financial Conflicts of Interest in Sponsored Research.

Harvard University has the obligation to identify potential conflicts of interest and to manage, reduce or eliminate identified conflicts. The University FCOI Policy states,

> 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.
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> 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 internally disclosing them, that disclosed 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.

This justification is further buttressed by regulatory obligations arising out of the research support that Harvard receives from the federal government.

Outside Activity Reporting Process

Who is required to submit an outside activity report?

All individuals with an HMS appointment and all individuals designated as an Investigator or Covered Individual (collectively "Researchers") on a research project for which an application for funding has been made through and/or granted to HMS must report their outside professional activities and financial interests (including relevant interests held by their partner/spouse or dependent children) to HMS at least annually. For HMS affiliated hospitals/institutions, HMS has delegated its responsibility to collect such reports on behalf of both the affiliated institution and HMS for individuals with primary appointments at the HMS affiliated hospital/institution.

HMS appointees whose primary appointment is with an HMS affiliated hospital/institution only need to report outside activities to the primary affiliated institution and do not need to separately report their outside activities or financial interests through the Harvard disclosure system. HMS will rely on its affiliated institutions to maintain primary custody of information that is required to be reported to HMS and to make such information available to HMS promptly upon request. Affiliated institutions are also obligated to submit annual summary reports to HMS as reasonably requested.

Individuals with joint or multiple appointments at Harvard will submit their disclosures to their primary school or unit. Circumstances may require that officials from other schools or units with which such individuals are affiliated may be granted access to the disclosures and may review the submissions as well. In either case, these internal confidential disclosures are held in confidence, and released only to those school officials with a need to know, as designated by each school's Dean. Schools maintain a secure process to obtain, review, eliminate, reduce or manage any identified conflict of interest whether potential, perceived or actual.

What to include

Faculty members and Researchers are required to report all external professional activities and financial interests with outside entities that are related to their institutional responsibilities to Harvard whether compensated or uncompensated. Individuals should disclose any relationships that rely upon the experiences and professional expertise that serve as any part of the basis for their HMS and/or affiliate appointment. Outside entities are those with which the faculty member or Researcher has a relationship outside of Harvard or one of its affiliate institutions. Outside entities include companies, service providers, non-government organizations (NGOs), foundations, foreign governments, and any other for-profit or not-for-profit entities with which the individual, their partner/spouse or dependent children (family) had a relationship in the last twelve months.

See OAIR What to Include for additional information about what types of activities should be disclosed.

Types of disclosures and review process

Faculty members and Researchers are required to submit their outside activity and financial interest disclosures through the Outside Activities and Interests Reporting (OAIR) system. There are three types of OAIR submissions (Annual, Update, and Research-Based), and while the submitter's experience is nearly identical in all three, each disclosure type serves a different purpose.

Annual Disclosures

In accordance with HMS and University COI policies, faculty members and Researchers are required to complete an annual disclosure certification regardless of whether any updates or research-project-based deadlines have arisen in the time since their last annual disclosure. The disclosure certification consists of questions about the individual's role at the University and their related outside financial interests and professional activities, with a reporting period covering the previous twelve months. If an individual has previously completed a disclosure submission, the data from the previous submission will be displayed in the system; the individual is required to review the information, remove interests and activities that ended before the disclosing period of the past 12 months, ensure the accuracy existing activities and interests, and add any new activities or interests that have arisen since the last submission. Officials from HMS will review the annual disclosure submission in accordance with the standards set forth in the HMS Policy on Conflicts of Interest and Commitment and the HMS/HSDM Policy on Conflicts of Interest in Sponsored Research.

Update Disclosures

Researchers participating in federally funded research must update their disclosures in accordance with the requirements set forth in the HMS/HSDM Policy on Conflicts of Interest in Sponsored Research[1]. The OAIR system will display previously submitted information and the discloser will only be obliged to create a new entry to report the new interest or activity.

Research Project Disclosures

For all individuals conducting research for which an application for funding has been made through and/or granted to Harvard Medical School, there are additional obligations to report financial interests and outside activities at the time of research proposal submission and time of award as described in the HMS/HSDM Policy on Conflicts of Interest in Sponsored Research.

At the time of research proposal submission to the sponsor, all Researchers on the project must have an up-to-date outside activity and interest report on file in the OAIR system. Researchers will receive an e-mail notification prompting them to review their disclosures and to update financial interests and outside activities, if necessary. If the disclosure is accurate and complete, no further action is required at the time of proposal submission. If the Researcher does not

[1] The disclosure update requirements vary by funding agency for federally funded research projects. The Public Health Service requires submission of disclosure updates within 30 days of acquiring a new Significant Financial Interest. The Department of Energy requires submission of disclosure updates within 15 days of acquiring a new Conflict of Interest or Conflict of Commitment.

have a current disclosure on file in the OAIR system, the Researcher will be required to submit a disclosure prior to submission of the research proposal.

If the project is awarded funding, each Researcher will be prompted by the OAIR system to submit a research certification, affirming that all disclosure information in the system is current. As with the Update Disclosures described above, all previously-entered information will already be populated in the form and the principal task of the Researcher is to ensure that it is accurate and up to date. Disclosures will be reviewed in accordance with the standards set forth in the HMS/HSDM Policy on Conflicts of Interest in Sponsored Research and the HMS Policy on Conflicts of Interest and Commitment.

Oversight and Governance

Each school's implementation of the University FCOI Policy, including this Implementation Plan, is subject to review and oversight by the University Standing Committee on Financial Conflicts of Interest, a long-standing faculty committee with representation from across the University. As part of that oversight, each school submits to the Office of the Vice Provost for Research an annual report on its FCOI Compliance, which is in turn presented to the Standing Committee for its review. This report details the rate of compliance at the school, the number of management plans currently in effect, and any noteworthy challenges or issues faced by the school in the past year. HMS relies on its affiliated hospitals/institutions to provide such information on behalf of HMS appointees with primary appointments at an HMS affiliated hospital/institution.