

Financial Interest Disclosure Requirements for University Faculty, NSF and PHS Investigators

- Please read each section below and sign under the Certification section at the bottom.
- Definitions for *italicized* terms follow the Certification as Appendix A.

1. University and Federal Policies Require Financial Interest Disclosure

- Harvard's Policy on Individual Financial Conflicts of Interest
 - o Covers all Faculty and holders of teaching appointments. (Schools determine when visiting and part time appointments are covered.)
 - Also, Principal Investigators and all those "responsible for design, conduct or reporting" of NSF, and Public Health Service (PHS) funded proposals and awards, including those agencies that follow PHS rules for COI (at 42 CFR Part 50, Subpart F). An up-to-date list of those agencies can be found online at http://sites.nationalacademies.org/PGA/fdp/PGA_070596).

2. Purpose of Policies and Definition of Conflict of Interest

- The University policy aims to protect the integrity of scholarship and research.
- The University policy defines a Financial Conflict of Interest as: "a set of circumstances that reasonable observers would believe creates an undue risk that an individual's judgment or actions regarding a primary interest of the University will be inappropriately influenced by a secondary financial interest."

3. Key Responsibilities of Faculty Members, Investigators, Schools and the University

- Faculty members, NSF and PHS Investigators (including agencies that follow 42 CFR Part 50, Subpart F) must make disclosures of Significant Financial Interests to their schools
- Faculty members must publicly disclose related financial interests in publications and presentations
- Schools must designate officials to review faculty and investigator disclosures for conflicts of interest, and, in collaboration with faculty members and investigators, plan how to manage any conflict
- The University maintains its policy, oversees its implementation, and makes required disclosures of conflicts

4. Internal Disclosure of Financial Interests

- Confidential disclosure to your School Designated Institutional Official of Significant Financial Interests in Related Outside Entities:
 - o Includes financial interests of spouse and dependent children
 - Includes
 - financial compensation, from consulting, employment, managerial, and fiduciary relationships that, when aggregated by entity over the preceding twelve months, exceeds \$5,000;
 - equity and other financial interests above \$5,000;

- equity interests of any amount, or entitlement to the same, in a non-publicly traded, for-profit, entity;
- intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income related to such rights and interests; and,
- for Investigators applying for or receiving funding from PHS or an agency following PHS rules for COI only, reimbursed or sponsored travel.

5. Internal Disclosure: Significant Financial Interests in Related Outside Entities

- Related Interests: Interests that may be perceived to influence your teaching, research or other University responsibilities
- Examples of entities in which an interest would be considered *related* include those:
 - o whose products, services or activities are related to the areas of your teaching or research
 - o that fund research in your area of academic interest
 - o that own or have rights to develop intellectual property that is the subject of research in which you participate

6. Examples of Related Outside Entities, cont'd

- that compete commercially with such an entity in which you have a financial interest
- that make or propose to make a gift to the University that would support your teaching or research activities
- that furnish products or services to the University through a contractual process in which you participate in any way
- that propose to enter a licensing agreement with the University with respect to technology invented by you

7. When to Disclose Significant Financial Interests

Disclose Significant Financial Interests:

- At least once annually (note that some Schools disclose at the same time each year)
- Within 30 days of acquiring a *new* related Significant Financial Interest

Disclosures must include all updates of *related* interests and be submitted within the year before submitting a sponsored proposal, licensing technology through OTD, or accepting a gift.

Harvard IRBs will ask you to disclose financial interests related to any human subjects research project within the IRB application process.

8. Disclosing Reimbursed or Sponsored Travel (PHS Investigators Only)

PHS Investigators, (including projects proposed for funding or funded by those additional agencies that follow 42 CFR Part 50, Subpart F):

- must disclose to their School any travel reimbursements received from an entity, or travel costs paid directly by an entity, related to their institutional responsibilities within 30 days of the travel. (Schools will specify what to disclose, e.g. purpose of trip, destination, sponsor).
- Disclosure is *not required* for Harvard-reimbursed travel or travel reimbursed or sponsored by:
 - o a federal, state, or local government agency,

- o an institution of higher education as defined at 20 U.S.C. 1001(a),
- o an academic teaching hospital,
- o a medical center, or
- o a research institute that is affiliated with an institution of higher education.

9. Public Disclosure by Investigators

- Once identified by your School's Designated Institutional Official, conflicts of interest must be managed, and public disclosure of such interests is likely to be part of any management plan
- Publicly disclose a financial interest of any amount when you believe reasonable audience members would give it weight in assessing what you are presenting
- Comply with journal disclosure rules about financial interests

10. Role of the Institution

Each School maintains a secure process:

- To obtain and review Investigator financial interest disclosures
- To develop management plans for any identified conflict of interest (or to require divestiture of an interest)
- To ensure that identified conflicts are reported according to federal regulations

The Harvard University Faculty Advisory Committee on Institutional Research Policies and the Office of the Provost oversee University-wide implementation of COI policy.

CERTIFICATION

I certify that I have read the Harvard University conflict of interest policy and the Financial Interest Disclosure Requirements above.

Signature: Click here to enter text.

Date: Click here to enter a date.

APPENDIX A: Definition of Key fCOI Terms (Last Updated: April 19, 2012)

Equity means stock, stock options, warrants or other ownership interest. You are not required to disclose equity held in diversified financial holdings such as mutual funds.

Family Member means spouse and dependent children. So far as the financial interests of family members bear upon the application of the University policy on financial conflicts of interest, a faculty member must affirmatively make inquiry into, and shall be presumed to know of, the financial interests of family members as herein defined.

Fiduciary or Management Role means service as an officer, director or service on an advisory board (including scientific advisory boards), whether paid or unpaid. Investigators may need prior approval from the Dean before assuming such responsibilities. "Fiduciary or management role" does not mean service on an editorial board. In their implementation plans, schools may extend this requirement to include service on the board or advisory panel of a not for profit entity.

Institutional Responsibilities means an individual's professional responsibilities on behalf of Harvard. Such responsibilities include, but are not limited to: research, research consultation, teaching, professional practice, institutional committee memberships, and service on committees or panels such as research ethics committees (e.g. Institutional Review Boards, Institutional Animal Care and Use Committees) and other bodies monitoring the conduct of research.

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

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 research¹

Related Outside Entity means an entity in which a person has a significant financial interest that may, or may reasonably appear to an outside observer, to influence the discharge of teaching, research, or other University-related responsibilities. In determining relatedness, individuals should employ a standard of common sense, and when in doubt, disclose. Examples of entities that might be related are those:

- (1) whose products, services or activities are related to the areas of a faculty member's or an investigator's teaching or research;
- (2) that fund research in a faculty member's or an investigator's area of academic interest;
- (3) that own or have rights to develop intellectual property that is the subject of research in which a faculty member or an investigator participates;
- (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 a faculty member's or an investigator's teaching or research activities;

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¹ "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. 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 the University policy. See 42 C.F.R. 50.602 (definition of "investigator").

- (6) that furnish products or services to the University through a contractual process in which a faculty member or an investigator participates in any way;
- (7) that propose to enter a licensing agreement with the University with respect to technology invented by the faculty member or investigator;
- (8) that act as a legal or de facto agent for any outside entity engaged in any of the above activities.

School Implementation Plans may define "related outside entity" beyond the definition provided above. You should consult your school's Plan carefully.

Significant Financial Interest includes, but is not limited to, (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. "Financial compensation" does not include, for example, interests of any amount in diversified financial holdings, or royalties or other remuneration paid by Harvard.

School Implementation Plans may define "significant financial interest" beyond the definition provided below. You should consult your school's Plan carefully.

Students means students, trainees, and post-doctoral fellows.