

SEAS PLAN FOR IMPLEMENTING HARVARD UNIVERSITY POLICY ON INDIVIDUAL FINANCIAL CONFLICTS OF INTEREST FOR PERSONS HOLDING FACULTY AND TEACHING APPOINTMENTS

I. INTRODUCTION

This Plan implements, on behalf of the School of Engineering and Applied Sciences (the "School"), the Harvard University Policy on Individual Financial Conflicts of Interest for Persons Holding Faculty and Teaching Appointments (the "University Policy"), as voted and approved by the President and Fellows of Harvard College on May 26, 2010. Holders of faculty and teaching appointments at the School are responsible for maintaining familiarity with the University Policy and this Plan and complying with both.

The following Governing Principles, as articulated in the University Policy, should guide the conduct of School faculty and all academic appointments and inform the application of this Plan:

- Society grants special privileges to universities and their faculty in return for their contributions, especially in fulfilling their role as independent arbiters of knowledge. With these privileges come special responsibilities and standards of conduct.

- Societal trust in the University depends upon the independence, integrity, and transparency of the University's endeavors. Accordingly, the University must practice responsible and vigilant self-governance to ensure that it remains trustworthy.

- The University's missions as well as the public interest are served by responsible interactions between faculty members and others (including government, business, and other organizations and individuals), with a view towards stimulating and nurturing research and education, the development and beneficial application of policies and technologies, and the pursuit of other scholarly and educational activities.

- Independent inquiry and the publication of scholarly findings are vital to the integrity and objectivity of research.

II. DEFINITION OF INDIVIDUAL FINANCIAL CONFLICT OF INTEREST

We define an individual 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.

It is important to understand that a financial conflict of interest is a matter of objective circumstance. It does not depend on the character or actions of the individual. It exists (or does not exist) regardless of whether it is operative, that is, whether it is in fact influencing an individual's judgment or actions. *To recognize the existence of a financial conflict of interest is not to pass judgment on the character or actions of an individual and does not, per se, imply wrongdoing.*

III. STANDARDS OF CONDUCT

III.A. Avoidance of Financially Conflicting Interests.

The educational and research activities of the University should be motivated primarily by a concern for the advancement of knowledge and the pursuit of truth. Accordingly, faculty members should not permit outside activities and financial interests to compromise their primary commitment to the missions of the University and to the highest intellectual and ethical standards in discharging their academic responsibilities. They should refrain from actions that could reasonably bring discredit upon Harvard and their own academic and scholarly integrity, and they should avoid circumstances that reasonable observers would believe create an undue risk that the prospect of direct or indirect personal financial gain could inappropriately influence faculty members' judgment or actions in fulfilling their University duties.

III.B. Compliance with Laws.

Faculty members are expected to comply with all state and federal requirements applicable to financial interests in research or other academic activities, including but not limited to licensure and professional conduct standards, financial disclosure requirements, laws concerning "finder's fees" for research subjects, prohibitions against insider trading, and statutes and regulations concerning conflicts of interest.

III.C. Free Inquiry and Intellectual Exchange.

The free and open exchange of ideas and the results of scholarly activities are the essence of academic freedom and are fundamental to the integrity of the University as a community of scholars. Faculty members must foster an atmosphere of academic

freedom by promoting the free, open, and timely exchange of results of scholarly activities. Financial conflicts of interest cannot be permitted to undermine independent inquiry or uncensored publication of ideas and findings.

III.D. Instruction and Advising of Students.

The student-faculty relationship lies at the heart of the academic enterprise. A faculty member's outside financial interests should not adversely influence his or her instruction, guidance, or supervision of students, trainees, or post-doctoral fellows. Academic assignments to students, trainees, and post-doctoral fellows should principally serve their interests in learning, self-development, and satisfaction of requirements for academic advancement. Faculty should not assign students, trainees, or post-doctoral fellows to participate in research projects or other scholarly projects that constrain or could constrain their ability freely to discuss, defend, and publish their research. Without the prior approval of the Dean, no faculty member may assign any student, trainee, or post-doctoral fellow to any research project or other scholarly project in which the faculty member or a member of his or her family has a financial interest directly or through an outside entity. Furthermore, a faculty member must ensure that the work of students, trainees, and post-doctoral fellows is not exploited in service of the faculty member's outside activities.

III.E. Supervisory Responsibility.

Faculty members in positions of academic seniority or administrative authority must maintain the highest level of ethical integrity in carrying out their supervisory responsibilities. A faculty member's outside financial interests should not influence his or her supervision, mentoring, evaluation, or direction of other faculty or staff. Faculty must not exploit tenure-track or non-ladder faculty or staff in service of the faculty members' outside activities or otherwise to realize personal financial gain.

III.F. Public Disclosure.

When conflicts of interest are identified and managed, public disclosure will be an element of management plans. Faculty members must make public disclosures of related financial interests and sources of support when, in their judgment, reasonable members of the audience would give weight to those interests in assessing the opinions, advice, or work they are presenting. Faculty members are also expected to comply with the disclosure requirements of their professional journals and societies.

Public disclosure of related financial interests is particularly important when faculty members are sought as experts to inform the public on matters of concern and to help shape public policy.

III.G. Use of University Resources.

Faculty members may not use University resources, including confidential information or - other than in a purely incidental way - facilities, personnel, or equipment to support their outside consulting activities or for any other purposes that are unrelated to the education, research, scholarship, and public service missions of the University. Use of the Harvard name by faculty members must comply with regulations set forth in existing University policies. Use for personal profit of unpublished information emanating from University research or other confidential University sources, or assisting an outside organization by giving it exclusive access to such information, is prohibited.

IV. IMPLEMENTATION DETAILS

IV.A. Definitions.

- *Academic Activity* means research, scholarship, teaching, University service, or public service in which a Covered Individual engages in conjunction with his or her University duties.
- *Conduct Research* means participation in the direction, design, implementation, analysis, or reporting of research, and, when human research participants are involved, in the enrollment of subjects and determination of their initial and continuing eligibility to participate.
- *Covered Individual* means an individual holding a ladder/non-ladder faculty or teaching appointment, full- or part-time, or paid research appointments at the School.
 - In the circumstances specified in paragraph five of section IV.C below, Covered Individual shall include an individual holding a visiting faculty or teaching appointment or an un-paid research appointment at the School.

[NOTE: *SEAS faculty members who also serve as core faculty members of the Wyss Institute, or any SEAS faculty member/researcher undertaking clinical research (Clinical research may be defined as investigations involving human subjects or the use of patient samples) will be required to use the Harvard Medical School's fCOI Disclosure procedures*]
- *Designated Institutional Official* ("DIO") means the Associate Dean for Research and Planning. He/she will oversee and be accountable for the general implementation and enforcement of the Implementation Plan, and will discharge responsibilities pursuant to applicable laws and regulations pertaining to financial conflict of interest.
- *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 this implementation guide.

- *Equity* means stock, stock options, warrants or other ownership interest.
- *Family Member* means spouse and/or dependent children. Insofar as the financial interests of family members bear upon the application of this policy, a faculty member must affirmatively make inquiry into, and shall be presumed to know of, the financial interests of family members as defined herein.
- *Fiduciary or Management Role* means service as an officer, director or service on an advisory board (including scientific advisory boards). 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.
- *Financial Conflict of Interest* is 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.
- *Financially Conflicted Individual* means a Covered Individual who has been determined by the DIO to have a Financial Conflict of Interest.
- *Human Subjects Research* includes all research meeting the definition of "research" performed with "human subjects", as these terms are defined in the federal Common Rule (45 C.F.R. Part 46 [Public Health Service] and 21 C.F.R. Part 56 [Food and Drug Administration]), regardless of the source of research funding or whether the research is otherwise subject to federal regulation.
- *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.
- *Investigator* means the project director or principal investigator or any other person, regardless of title or position, who is responsible for the design, conduct, and/or reporting of research.

- *Related Academic Activity* refers to an Academic Activity whose performance, as viewed by a reasonable observer, could be affected by a Covered Individual's outside financial interests.
- *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, report. Examples of entities that might, or might appear to, exercise influence include those:
 - whose products, services, or activities are related to the areas of a faculty member's or an investigator's teaching or research;
 - that fund research in a faculty member's or an investigator's area of academic interest;
 - that own or have rights to develop intellectual property that is the subject of research in which a faculty member or an investigator participates;
 - that compete commercially with such an entity as described in the previous provision;
 - 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;
 - that furnish products or services to the University through a contractual process in which a faculty member or an investigator participates in any way;
 - that propose to enter a licensing agreement with the University with respect to technology invented by the faculty member or investigator;
 - that act as a legal or de facto agent for any outside entity engaged in any of the above activities.
- *Significant Financial Interest (SFI)* 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. But, *only* when such interests are in an entity in which your significant financial interest may, or may reasonably appear to an outside observer to, influence the discharge of teaching, research, or other University-related responsibilities. This includes entities:
 - whose products, services or activities are related to the areas of your teaching or research;
 - that fund research in your area of academic interest;

- that own or have rights to develop intellectual property that is the subject of research in which you participate;
 - that compete commercially with such an entity as described in (3) above;
 - 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;
 - that act as a legal or *de facto* agent for any outside entity engaged in any of the above activities.
- Financial Compensation does not include, for example, interests of any amount in diversified financial holdings, or royalties or other remuneration paid by Harvard.
 - “Students” means Harvard University students, trainees, and post-doctoral fellows; including visiting students and fellows.

IV.B. Designated Institutional Official.

1. Appointment: Federal rules require PHS- and NSF-funded institutions to appoint an institutional official to review financial interests in agency-sponsored research. To meet this requirement, the Associate Dean for Research and Planning shall serve as the Designated Institutional Official ("DIO") who shall also be responsible and accountable for the implementation of this Plan. The DIO may be assisted by other School officials and by a standing faculty Committee on Conflicts of Interest.

2. Responsibilities: The DIO shall be responsible for performing the following functions:

- *Review disclosures* of financial interests submitted by Covered Individuals annually as well as disclosures submitted by investigators on PHS- and NSF-funded projects.
- *Review requests* from Covered Individuals to reconsider DIO decisions concerning disclosed financial interests.
- *Formulate recommendations* for disposition of financial conflicts of interest (fCOI), including management and oversight plans.
 - Category I Review: The DIO will ascertain whether the disclosed SFI represents a potential financial conflict of interest. This initial review is performed by the DIO, who, in situations where more information

is needed, will consult with the faculty member or the investigator. If the DIO and the faculty member agree that a potential fCOI exists, they will work jointly to implement preventative measures or develop a formal plan to manage, reduce, or eliminate the potential fCOI.

- Category II Review: In situations in which the DIO and the faculty member cannot agree on whether a potential fCOI exists, or cannot agree on appropriate measures to address the potential fCOI, the DIO will consult with a SEAS standing Committee on Conflict of Interest (COIC), comprised of two faculty members designated by the Dean. The COIC will be chaired by the Executive Dean for Administration, who is also the highest ranking SEAS administrative official responsible for managing faculty conflicts of commitment and finance. Additionally, this review committee may invite the Area Dean of the faculty member/PI to serve as a domain expert, and may consult with appropriate domain experts in specific administrative areas (e.g., SEAS Finance, SEAS Academic Affairs, or the FAS DIO) within the limits of confidentiality. This committee will develop recommendations and work with the faculty member to implement the recommendations and resolve the potential conflict. The SEAS COIC committee will send a final recommendation to the Dean, and the decision of the Dean will be final and binding. In the event that the faculty member and the SEAS COIC cannot come to an agreement, the Committee or the Dean can escalate the review to the FAS fCOI Committee, at which point the review will follow the FAS fCOI management process.
- *Prepare a summary report*, in any instance in which a Covered Individual is determined to have a Financial Conflict of Interest, which documents the DIO's findings (including findings upon reconsideration), the basis for the findings, and the disposition of the conflict of interest; including plans for management and oversight.
- *Provide copies* of the summary report, or portions thereof, to institutional officials and bodies with a need to know (e.g., Institutional Review Board, Institutional Animal Care and Use Committee, Office of Technology Development).
- *Oversee* and be accountable for the implementation and enforcement of this Plan, and recommend modifications of the Plan to enhance its effectiveness.

IV.C. Internal Confidential Disclosure of Significant Financial Interests

1. Annual disclosure and certification. Upon initial appointment¹ and, thereafter, on or

¹ The deadline is June 30, 2012 at launch of this new disclosure plan.

before July 15 of each year, Covered Individuals shall disclose electronically their Significant Financial Interests, using the prescribed disclosure mechanism. (Covered Individuals who are "Senior Officials" within the meaning of the "Harvard University Policy on Conflicts of Interest and Commitment for Senior Officers and Administrators" are exempt from disclosure obligations under this Plan but must annually file with the Office of the General Counsel the disclosures required by the cited policy.) The School reserves the right to request additional information and supporting documentation as needed. Covered Individuals who have no Significant Financial Interests shall certify to that fact in their disclosures. Covered Individuals shall also affirm in their disclosures that they have reviewed, and are in compliance with, the requirements of the "Harvard University Policy on Individual Financial Conflicts of Interest for Persons Holding Faculty and Teaching Appointments" and with this Plan.

2. Updates of annual disclosures. Covered Individuals shall update their annual disclosures of financial interests promptly upon becoming aware of circumstances, existing or reasonably anticipated, that would cause their original disclosures to be materially incomplete or inaccurate. Updates to disclosures are required within 30 days of the discovery or acquisition of a new financial interest and prior to accepting gifts, submitting an application for a sponsored project, or initiating a technology licensing agreement. Whenever possible, Covered Individuals should submit updates in advance of material changes in order to permit timely review by the DIO.

No sponsored research proposal should be submitted to the Office of Sponsored Programs (or, in the case of research to be covered by an industry-sponsored agreement, to the Office of Technology Development) unless each faculty member participating in the research project (and in the case of proposals for Public Health Service funding, any investigator) has certified to having filed an accurate and up-to-date annual disclosure. The OSP will not transmit such a proposal and the OTD will not sign such an agreement without such certifications.

3. Disclosure obligations. Covered Individuals are expected to be diligent in compiling and disclosing their financial interests in a timely manner (reviewing their financial records, making inquiries of family members, verifying data with outside entities as necessary, and so forth). *If uncertain about any aspect of their disclosure obligations, Covered Individuals should seek guidance from the DIO.* Failure to make good faith efforts to file timely, accurate, and complete disclosures and certifications (annual or ad hoc) is unacceptable and constitutes grounds for sanctions.

4. Managerial and fiduciary relationships. Because relationships that involve managerial or fiduciary responsibilities may give rise to irremediable financial conflicts of interest, and because unwinding these relationships can be awkward and difficult, faculty members shall obtain prior approval from the Dean before assuming such responsibilities.

5. Non-Ladder Teaching Appointments/Visiting Faculty/Research Appointments. Holders of visiting faculty, teaching, or research appointments, paid or unpaid, whose appointments require them to participate in academic duties within the School for six months or longer shall disclose any Significant Financial Interests that are directly related to their Harvard responsibilities. Regardless

of the length of time of their participation in duties at Harvard, visiting faculty are required to comply with the requirements of paragraph 3 above in the case of any Significant Financial Interests or that pertain to transactions that arise during their Harvard service.

6. For PHS Funded Research ONLY. Travel reimbursements from external private entities, such as industrial collaborators, must be reported in accordance to PHS/University policies using procedures established by the DIO and will be disclosed according to the same standard as the other disclosures (*see University COI Policy*).

IV.D. Review and Handling of Annual Disclosures

1. Review. The DIO, assisted by the COIC as needed, shall review all disclosures of significant financial interests (including updates) submitted by Covered Individuals and, based upon the submitted information and whatever supplemental information the DIO requires, identify any disclosed interests that give rise to Financial Conflicts of Interest. If the DIO or any COIC member has a conflict of interest in reviewing reported information, he or she shall immediately recuse himself or herself, inform his or her superior, and request that the review be performed by a disinterested alternate.

2. Confidentiality. Disclosures of financial interests shall be collected and maintained in a secure format, held in confidence, and released only to the DIO, the COIC, and School and University officials and entities with a need to know, or as otherwise authorized by this Plan² [*Note that disclosures using the Harvard Medical School's (HMS) reporting process will be subject to standards of confidentiality set by HMS*].

3. Principles for evaluating financial interests. Whether a financial interest gives rise to a financial conflict depends upon the objective circumstances and not upon the state of mind of the Covered Individual. The test is whether reasonable observers would believe the presented circumstances create an undue risk that the financial interest may inappropriately influence the Covered Individual's judgment and actions concerning the University's primary interests in independent and objective scholarship, furtherance of students' educational interests, protection of human research participants and animal research subjects, and the like.

4. Disposition of financial conflicts of interest. If the process of review leads to the finding that a Financial Conflict of Interest exists, the DIO shall decide whether to (1)

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.

eliminate the conflict, for example, by requiring that the Financially Conflicted Individual either divest the financial interest or refrain from engaging in the Related Academic Activity, (2) reduce the interest below the level that the DIO deems of concern for the Related Academic Activity at issue, for example, by requiring that the Financially Conflicted Individual forego receipt of a portion of outside income, or (3) permit the Financially Conflicted Individual to proceed with the Related Academic Activity under terms or conditions designed effectively to manage and minimize the associated risks. In determining the appropriate response, the DIO and/or the COIC must consider the extent to which the financial interest is amenable to elimination, reduction, or credible oversight and management. Among the circumstances that the DIO should evaluate are: the nature of the Related Academic Activity; the magnitude of the financial interest and the degree to which it is related to the Related Academic Activity; the extent to which the financial interest could be directly and substantially affected by the Related Academic Activity; the degree of risk inherent in the related Academic Activity to involved individuals, to the University, or to public safety and well-being, including risks to reputation and to the University's core missions and values; any risks to the rights of and obligations to students, fellows, and trainees; the benefit to the University community or general public of permitting the individual to participate in the Related Academic Activity; whether the individual has unique expertise or brings other unique resources to the Related Academic Activity; the harm or loss that would result from prohibiting the Financially Conflicted Individual from participating in the Related Academic Activity.

5. Notification, reconsideration, and appeal. The Dean shall notify Financially Conflicted Individuals of findings and decisions concerning Financial Conflicts of Interest, the disposition of the conflict, and the terms and conditions of any management plan. If the Dean overturns the DIO's or the COIC's final recommendations, the Dean shall retain documentation on the basis of his or her decision and shall furnish a copy to the FAS Dean and Vice Provost for Research.

6. Documentation. With respect to every reported financial interest determined to constitute a Financial Conflict of Interest, the DIO shall prepare a written report summarizing the nature and amount of the financial interest, the DIO's and the COIC findings (including findings upon reconsideration), the bases for the findings, the disposition of the conflict, the terms of any plan for management or reduction of the financial interest, and any other actions taken. In addition, the DIO shall annually prepare a report for submission to the FAS DIO and Vice Provost for Research describing all conflicts of interest identified during the year, how they were resolved (including terms of management plans), and any sanctions imposed or other actions taken.

7. Consultation with the Vice Provost for Research. When dealing with a financial conflict of interest of unusual significance due to its complexity, magnitude, notoriety, or precedential impact, the Dean and/or the DIO may consult with the FAS DIO/Vice Provost for Research / or the Chair of the University Standing Committee on Conflict of Interest in advance of making a final determination concerning the disposition of the conflict of interest or other remedial actions.

IV.E. Management and Oversight of Conflicts.

1. Acknowledgement of management plan. Each management plan shall be agreed to and signed by the Financially Conflicted Individual before he/she is permitted to proceed with the Related Academic Activity. The DIO shall retain a copy of the signed management plan.

2. Objectives of management plans. Plans for ongoing oversight or monitoring of Related Academic Activity following the identification of a Financial Conflict of Interest should be designed to protect the integrity of the academic activity, the integrity of the educational experience for students; the welfare of human research participants and research animals; and the reputations of involved faculty, the School, and the University. Among other things to be considered in the development of management and oversight plans are the following:

- What risks are to be mitigated (e.g., biased scholarship, exploitation of students, tenure-track or non-ladder faculty, inappropriate use of University resources, unnecessary exposure to harm of human or animal research subjects)?
- How can the interests of students and tenure-track faculty best be protected?
- Can the conflicting financial interest be reduced or placed under the control of a disinterested trustee?
- To whom should the conflicting financial interest be disclosed in order to ensure transparency and protect the interests of third parties and the public?
- To what extent can the Financially Conflicted Individual be excluded from sensitive aspects of the Related Academic Activity (e.g., enrollment of human research participants, design of survey instruments, evaluation of student performance)? Can these aspects be handled by individuals not subject to the control or influence of the Financially Conflicted Individual?
- Is effective oversight or monitoring of the Related Academic Activity feasible by individuals within the School or external to the School or University?

3. Oversight of management plans. The DIO must ensure that the management plan is being followed and should periodically audit the Related Academic Activity to ensure that the plan is practical and effective. If the management plan involves monitoring the activity of the Financially Conflicted Individual, the monitor(s) should report to the DIO at regular intervals concerning the Individual's compliance with the elements of the management plan.

4. Public Disclosure. As a precondition to participating in Related Academic Activity in which a faculty member has a conflicting interest, a management plan may require a faculty member to disclose his or her conflicting interest:

- a)To all participants in the Related Academic Activity, including students and trainees;

- b) To prospective students, trainees, and new faculty before such individuals make a decision to participate in the Related Academic Activity,
- c) To funders and sponsors of the Related Academic Activity;
- d) To human research participants, as determined by an Institutional Review Board;
- e) To state and federal officials, as required by statute or regulation; or
- f) To other parties as deemed appropriate in the circumstances (e.g., advisees, students, general public). If the Related Academic Activity involves a multi-institutional collaboration, the existence of the Financial Conflict of Interest may be required to be made known to the collaborating investigators, the sponsor, and appropriate officials of the other institutions participating in the Related Academic activity.

IV.F. Education and Training.

The DIO, in consultation with the COIC, the FAS DIO, and the Vice Provost for Research, shall develop and disseminate materials to educate faculty about financial conflict of interest concerns in general and the requirements of the University Policy and the School's Implementation Plan in particular.

IV.G. Sanctions.

1. Covered Individuals are expected to comply with the University Policy, the Standards of Conduct and Implementation Details set forth in this document, and management plans imposed by the DIO in connection with any Financial Conflict of Interest.
2. Appropriate sanctions may be imposed on a Covered Individual for failure to comply with any of the above.

APPENDIX I: EXAMPLES ONLY

Exhibit One: Examples of Possible Financial Conflicts of Interest

1. An investigator has equity interest or receives income from an entity whose business interests are related to research conducted in the investigator's Harvard laboratory.
2. An investigator is a consultant to the company sponsoring research in his or her laboratory.
3. A Senior Investigator has:
 - a. A significant ownership interest in the sponsor.
 - b. The opportunity to receive substantial financial benefits from the sponsor (e.g., bonuses, stock options).
 - c. A long term or ongoing consulting relationship with the sponsor.
4. The Principal Investigator of a project also has a significant equity interest in a small start-up company:
 - a. The company now wants to sponsor research on campus, which involves the testing and improvement of its proprietary equipment, on loan for the duration of the project, as a part of a graduate student thesis project.
 - b. This is conflicted because the PI of the project has significant ownership and the Harvard-based work could affect the value of that ownership.
 - c. The conflict is even more significant because a graduate student is involved in the work.
5. The investigator is a founder, an owner or has another position managing the research or commercial direction of the company sponsoring his or her research. A potential conflict of interest may exist depending on several factors such as:
 - a. The extent of the investigator's equity holdings in the company, or the investigator's role in the company, e.g., is the investigator directing the research agenda or has this been transferred to regular management?
 - b. Does a member of the investigator's family have any managerial position with the company?
 - c. Is the investigator serving as a paid consultant

to the company? If so, how closely?

d. Does the research project overlap with the immediate commercial interests of the company sponsoring the research?

6. A University employee owns a company, hires a student(s) to work for that company, and has supervisory responsibility over the student's activities both at Harvard University and at the workplace.

7. A University employee is a principal investigator on a project and subcontracts to his or her private company.

8. A University employee owns a company that may be doing business with the University and makes purchases from that company through a contract or grant.

9. The University purchases goods or services from a business in which the University employee, or his or her family, has a financial interest.

10. The Investigator publishes an article in either an academic or non-academic journal that does not require fCOI disclosures and the Investigator has an equity interest that is related to the subject matter of the article.

Exhibit Two: Examples of Ways to Manage, Reduce or Eliminate Conflicts of Interest Research

1. Public disclosure of conflicts of interest to journals to which publications about the research are submitted or in public presentations of the research:

a. Example of management plan statement: I will disclose my relationship with (business entity) to all journals to which publications based on this research are sent, and in all public presentations of this research.

b. How to do it: The following are examples of statements that may be made in letters to journal editors, in the acknowledgements sections of articles, in PowerPoint presentations, on posters, verbally, etc., as appropriate to the situation.

- i. Dr. X is a consultant for XYZ Corporation, which funded this research.
- ii. Professor Y has a significant financial interest in ABC Corp., Inc. that provided the materials being tested in this research.
- iii. Professor Z is a co-owner of 123 Inc. that licenses technology she invented that is used in this research.

2. Evaluation of/disclosure to subordinates/students:

a. Example of a management plan statement: Subordinates will not be evaluated based on their participation (or lack thereof) in activities related to (business entity).

b. How to do it:

- i. If subordinates (e.g., tenure-track faculty, non-ladder teaching appointments, students, staff) will not be involved in the activities related to the business entity, state that clearly.
- ii. If subordinates are involved in activities related to the business entity, describe how you will avoid evaluating them based on their participation or lack thereof. For example, if the business entity is funding the research and

students are working on the project, describe exactly how they will be evaluated.

iii. I will disclose any conflict of interest for this project to students working on it as part of their studies, to the other members of the student's thesis committee (if relevant) and to the chair of the department, or, in the case of a chair with a conflict of interest for the project, to the chair of the department's graduate committee. I will notify students that, if they have any concerns about their participation, based on my conflict of interest, they can discuss those concerns with either the department chair or the chair of the department's graduate committee.

c. How to do it:

- i. Describe how you will notify students and others of your conflict.

Following is a sample letter:

Dear Students and Committee Members,
I am writing to officially inform you of a conflict of interest I have in regards to PROJECT NAME. As you may already know, I [DESCRIBE RELATIONSHIP TO COMPANY, e.g. "am part owner of XYZ Corp" or "receive compensation from ABC Corp for consulting" etc.] Since this company stands to profit from this work, and since I stand to profit from the company, I have a "conflict of interest", which has been officially disclosed to the University. As part of my disclosure to the University, I am informing you about this conflict. I encourage the members of your committee to ensure that I handle this conflict with appropriate professionalism. If you have any other concerns, please feel free to discuss them with me, any other member of your committee, the department chair, or the chair of the DEPARTMENT NAME graduate committee.

3. Blinding of data or analyst(s):

a. Example of a management plan statement:
The person who analyzes the data/samples will be blinded to the assignment of the data/samples to case or control group. Analysis will be conducted by a non-conflicted member of the research team who does not have access to the assignment information.

b. How to do it: Describe which member of the team will do the analysis and confirm that he or she has no conflict of interest for this project.

4. Modification of the research plan (where human subjects are involved), in addition to any other measures that may be required:

a. Example of a management plan statement: The conflict will be disclosed to all potential research participants in the consent process and consent documents.

b. How to do it (language for consent documents):

i. The [ROLE, such as PI, coordinator, nurse, etc.] for this project has a significant financial interest in (NAME OF COMPANY) the (TYPE OF COMPANY, such as the sponsor, lab, test supplier, etc) as determined by Harvard University's Conflict of Interest policy.

C. Examples:

i. The coordinator for this project has a significant financial interest in the sponsor, as determined by the Harvard University Conflict of Interest policy.

ii. The co-investigator for this project has a significant financial interest in the company that is providing the educational materials, as determined by the Harvard University Conflict of Interest policy.

5. Monitoring of research by independent reviewers:

a. Examples of management plan statements:

- i. Dr. X, who does not have a conflict of interest for this project, will advise and consent on all major research decisions.
- ii. Dr. Y, who does not have a conflict of interest for this project, will review the research and results every (interval).
- iii. How to do it: Describe Dr. X or Y's credentials and why he/she is appropriate as a monitor of your research. Describe what Dr. X or Y will review and how often. Provide written confirmation that the suggested monitor agrees to take on this role.

6. Conduct of all or part of the research by another, non-conflicted member of the research team or by a third party:

a. Examples of management plan statements:

- i. Consent of research subjects will be conducted by (name, position), a non-conflicted member of the research-team.
- ii. Surgery on the animals will be performed at a PHS-assured research organization with which no member of the research team has a conflict.

b. How to do it: Inform FAS IACUC administration (IACUC@fas.harvard.edu) prior to outsourcing animal work for Harvard research projects. Identify the non-conflicted person/entity taking over the research function, and provide documentation that they will take it on.

7. Divestiture of financial interests that present conflicts of interest:

a. Examples of management plan statements:

- i. I will sell my shares (or reduce my shares to below \$5,000) in (business entity) prior to the start of the project.
- ii. I will reduce my consulting for (business entity) to less than \$5,000/year for the duration of this project.

b. How to do it: Confirm the action with the Chair of the COIC.

8. Severance of relationships that present conflicts of interest:

a. Examples of management plan statements:

i. I will resign my position as officer/director/agent/employee of (business entity).

ii. I will not consult for (business entity) until this project is completed.

APPENDIX II:

Summary of key components in the SEAS Implementation of fCOI Policy

