



MASSACHUSETTS INSTITUTE OF TECHNOLOGY
Investigator Financial Disclosure Policy

Policy Summary

Whenever an investigator has a significant financial interest in a company or other organization that might reasonably appear to be affected by the investigator's research, there is the potential for a conflict of interest. Starting October 1, 1995, Federal regulations require that the existence of a conflict of interest or the potential for a perceived conflict of interest of an investigator (or his or her immediate relatives) be disclosed to the Institute when the investigator applies for or receives support from certain federal agencies.¹

Under the federal government's and MIT's policy:

- ◆ Financial interest means anything of monetary value, including but not limited to salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options, or other ownership interests); intellectual property rights (e.g., patents, copyrights and royalties from such rights).
 - In the case of salaries, royalties, or other payments, an interest is defined as “significant” if it is, or is expected to exceed \$10,000 during a 12 months period, when aggregated for the investigator, the investigator's spouse, and dependent children.
 - In the case of equity, interest is defined as “significant” if it is, or is expected to be (i) worth in excess of \$10,000 or ii) represents more than a 5% ownership interest in any single entity.
- ◆ The investigator's salary and any royalties from MIT and income from seminars, lectures, or teaching engagements for public or nonprofit entities are not included in the disclosure requirements. MIT has also determined that investments in mutual funds and in MIT tax deferred annuities and pension funds do not need to be disclosed.

To comply with the law and derivative federal regulations, Institute policy requires the following actions from principal investigators, co-principal investigators, and others responsible for the design, conduct, or reporting of research:

- ◆ Completion and submission of a financial disclosure for each proposal requesting support from either the National Science Foundation or the Public Health Service
- ◆ An annual certification is required from all investigators with current awards or pending proposals (to be submitted as part of the annual Outside Professional Activity report)

The financial interest disclosure is to be made via Coeus to the Director of OSP (Michelle Christy). If upon review there appears to be a potential conflict that needs to be addressed, the Vice

¹ Currently these agencies are the National Science Foundation and the Public Health Service (including NIH, NIOSH, CDC, and other PHS organizations). OSP can provide a complete list of PHS entities, upon request.

President for Research will involve the department chair/laboratory director in reviewing and making a determination of potential conflict and initiate steps to manage or eliminate the conflict(s) when appropriate. Except to the extent required by law, the information disclosed will be kept confidential.

At the present time only the National Science Foundation and the Public Health Service have issued final regulations. In general, these regulations require a principal investigator to disclose the existence of certain financial interests to the institution, who in turn, is responsible for reviewing the information and making a determination of a real or perceived conflict of interest exists, and how the conflict should be managed, reduced or eliminated. It is important to recognize that the disclosure of financial relationships provides a measure of protection for both the investigator and the Institute. The Institute is required to report to the NIH when a real or potential conflict of interest exists, whereas NSF requires that the Institute report the conflict only in cases where it cannot be managed, reduced or eliminated.

Principal and co-principal investigators, and others responsible for the design, conduct and reporting of research are required to complete a financial disclosure prior to submission of the research proposal to NSF, PHS and other agencies as required. All disclosures are filed on-line through CoeusLite as follows:

CoeusLite Site - <http://coeus.mit.edu/>

Instructions for filing proposal disclosures - http://coeus.mit.edu/training/COI_Screens_QC.pdf

Instructions for filing annual disclosures

http://coeus.mit.edu/training/COI_Annual_userguide.doc

If you have any questions about MIT's conflict of interest policy, please contact either Michelle Christy at extension 4-9022, Thomas Duff at 3-2762 or Claude Canizares at 3-3206.

Questions regarding the submission process and use of Coeus Lite should be directed to coeus-help@mit.edu

END

The following provides additional information and guidance regarding MIT's conflict of interest policy.

Definitions

Investigator means the principal investigator, co-principal investigator(s), key personnel and any other person at the institution who is responsible for the design, conduct, or reporting of research or educational activities funded or proposed for funding by NSF or PHS.² For purposes of the requirements of this definition relating to financial interests "Investigator" includes the

² MIT does not include graduate students or persons with postdoctoral appointments in the definition of investigator, unless such individuals are listed in the proposal as co-investigator(s) or key persons.

investigator's spouse and dependent children.

Significant financial interest means anything of monetary value, including but not limited to salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights). Stock in companies which have not yet undergone a public offering should be valued at the last sale price recognized by the company--not at the share price originally paid by the investigator. This price should be obtained by contacting the company, and should be updated annually at the time of reporting. The term does not include:

- ◆ salary, royalties or other remuneration from MIT;
- ◆ income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
- ◆ income from service on advisory committees or review panels for public or nonprofit entities; or
- ◆ an equity interest that, when aggregated for the investigator and the investigator's spouse and dependent children, meets both of the following tests: does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a 5% ownership interest in any single entity; or
- ◆ salary, royalties, or other payments that, when aggregated for the investigator and the investigator's spouse and dependent children, are not expected to exceed \$10,000 during the next twelve month period.

Institutional Responsibilities

NSF and PHS require institutions to develop and maintain an appropriate written and enforced policy on conflict of interest that complies with at least the following minimum requirements: (a) limited and targeted financial disclosures, (b) designation of a person(s) to review the disclosures, determine whether potential conflicts exist, and resolve them; (c) methods to manage conflicts of interest/enforcement mechanisms, (d) arrangements for informing PHS of all conflict situations and NSF of any conflict situation that is not resolved to the satisfaction of the institution, and (e) record retention procedures. Specific MIT procedures developed to meet these institutional responsibilities are detailed below:

◆ *Limited and targeted financial disclosures*

Financial disclosures related to research proposed to NSF or PHS for funding must be submitted to the Director of OSP in advance of submission of the proposal to the agency. Specifically, an Investigator must disclose all significant financial interests (including those of the Investigator's spouse and dependent children)

- (i) that would reasonably appear to be affected by the research or educational activities funded by the agency to whom the proposal will be sent; or
- (ii) that are in entities whose financial interests would reasonably appear to be affected by such activities.

An investigator who has no significant financial interests [as defined above] is still required to complete the financial disclosure process, indicating the absence of any significant financial interests.

In addition, all disclosures must be updated during the pendency and/or period of the award on an annual basis. This is done at about the same time as the annual Outside Professional Activity report.

◆ *Review of Disclosures*

Initial review will be conducted by the Director of OSP who will review the information submitted. If the Investigator has disclosed any potential conflicts to OSP in the forms submitted, the Vice President for Research will work with the appropriate department chair/laboratory director to review the potential conflict and determine steps to resolve or mitigate the conflict. Reviews and resolutions of any conflict must be completed prior to the expenditure of funds on any award from NSF or PHS.

◆ *Methods to Manage Potential Conflict / Enforcement Mechanisms*

The reviewing officials are responsible for determining what mechanisms are appropriate for managing, reducing or eliminating conflicts of interest. Examples of conditions or restrictions that might be imposed to manage, reduce or eliminate conflicts of interest include:

- public disclosure of significant financial interests
- monitoring of research by independent reviewers
- modification of the research plan
- disqualification from participation in the portion of funded research that could be affected by the significant financial interests
- divestiture of significant financial interests
- severance of relationships that create actual or potential conflicts

◆ *Sanctions*

If an Investigator fails to comply with MIT's conflict of interest policy and the design, conduct, or reporting of the PHS-funded research has been biased the Institute will promptly notify the PHS awarding component of the corrective action taken or to be taken and PHS may direct the Institute on how to maintain appropriate objectivity in the funded project. These actions may include restrictions imposed on the individual with respect to submission of proposals and may also include the disciplinary sanctions referenced in section 3.3.2 of MIT's Policies and Procedures.

◆ *Arrangements for Informing NSF or PHS of conflict issues*

Most conflict of interest situations are resolvable. In the instances where they are not, however, the Institute must inform the sponsor. Both NSF and PHS have specific requirements for notification.

- ◆ NSF requires that prior to funding of an award MIT must either be able to satisfactorily manage, reduce or eliminate any conflict, or if it is not able to manage

such conflict must inform NSF. NSF permits the reviewer, in certain limited situations, to allow a conflict to continue.

- ◆ PHS regulations require that the Institute report to the PHS awarding component the "existence of a conflicting interest (but not the nature of the interest or other details) found by the institution and assure that the interest has been managed, reduced or eliminated." prior to the expenditure of funds.

Also, any interest that the Institute identifies as conflicting subsequent to the Institute's initial report under the award, will be managed, reduced, or eliminated and then reported to the sponsor in accordance with sponsor policy. The Office of Sponsored Programs is responsible for providing appropriate written notice to the sponsoring agency and, where appropriate, will request that the conflict be permitted to continue.

◆ *Record Retention*³

The Office of Sponsored Programs must maintain records of financial disclosures and all actions taken to resolve conflicts of interest until at least 3 years after the later of the submission of the final expenditure report to which they relate, or longer in certain other cases, such as the resolution of any government action involving those records.

◆ *Managing Subawards*

In cases where MIT is proposing to subcontract NSF or PHS funds to another organization (a subawardee), OSP will require certifications from the organization prior to submitting the proposal for review to the relevant agency. Coverage extends to all subawardees on PHS proposals, but only to subawardees with 50 or more employees for NSF. This requirement can be met through the subawardee providing MIT with

- a completed proposal certification page from the appropriate agency (e.g. PHS 398 or NSF1030), signed by the authorizing official of the subawardee, or
- a letter of certification what includes the certification language from the prime agency, signed by the authorizing official of the subawardee.

Signature from the Authorized Organizational Representative of the subawardee assures the Institute that the subawardee organization will comply with the sponsor's policies, including the financial conflict of interest requirements.

Subawardees and consultants are obligated to report identified financial conflicts of interest to MIT; MIT must report to the sponsor the existence of any conflicting interest(s) arising from these subawards and assure that the interest has been managed, reduced, or eliminated in accordance with sponsor policy.

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³ The length of time for record retention is specified. MIT has determined that the Office of Sponsored Programs will be responsible for maintaining the records of financial disclosures and actions taken. In addition, OSP is responsible for record disposal in accordance with these regulations.