

# **DRAFT GUIDELINES FOR FINANCIAL CONFLICTS OF INTEREST**

These guidelines are established to provide guidance on the Institute's policy on financial conflicts of interest that comply with federal regulations. An implicit assumption underlying these policies is that the design, conduct, and reporting of research should not be biased by any significant financial interest. Participation in research with opportunities for personal gain may not constitute an unacceptable situation. However, federal agencies have legitimate concerns that any research they sponsor is free of bias, due to financial interests of the investigator and institution. To qualify for federal funding, the university assumes the responsibility for ensuring that these concerns are addressed.<sup>1</sup>

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## Forms

- Financial Disclosure of Potential Conflict of Interest
- Conflict of Interest Management Plan Annual Review

## Related Institute Policies

- Financial Conflict of Interest Policy
- Outside Professional Activities
- Outside Employment

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<sup>1</sup> Current federal financial conflict of interest policies have been issued by the National Science Foundation (NSF) and the National Institutes of Health (NIH). Disclosure and management requirements currently apply to these agencies and will apply to other agencies when they adopt similar policies.

## **DEFINITIONS**

### **Conflict of Interest**

As defined by the federal government, a financial conflict of interest arises when an employee is involved in a particular activity as part of his/her official duties with an outside organization with which he/she also has a financial interest, or one which is imputed to him/her, (i.e., through the employee's spouse). Examples of relationships that need to be disclosed include when a researcher serves as an officer, director, trustee, partner, or employee of an organization other than MIT. Financial conflicts of interest can arise out of the fact that MIT's academic mission includes both research and the commercialization of technologies derived from that research. In all cases, an individual's actions or decision cannot be determined by consideration of personal financial gain, nor can the objectivity of research at MIT be influenced by a real or perceived financial conflict of interest.

### **Persons Responsible for the Design, Conduct, or Reporting of Research**

The federal guidelines and the Institute's policy apply to "persons responsible for the design, conduct, or reporting of research." In some cases, graduate students and postdoctoral fellows may be responsible for the design, conduct, or reporting of research, such that they are considered to be an investigator under this policy and may be required to complete disclosure statements. In any situation, it is the responsibility of the principal investigator to ensure that students and postdoctoral fellows are not diverted from their primary academic mission in any way.

### **Significant Financial Interests**

Financial interests in business enterprises or entities if the value of such interests: 1) exceeds \$10,000 per annum of salary, fees, and other payments when aggregated for the investigator and the investigator's spouse and dependent children; or 2) represents more than a five percent (5%) ownership interest in any one enterprise or entity when aggregated for the investigator and the investigator's spouse and dependent children.

## **GUIDING PRINCIPLES**

### **Financial conflict of interest situations should be avoided.**

- According to the Institute's financial conflict of interest policies, faculty should disclose any anticipated consulting or outside employment activities that meet the federal thresholds.
- Faculty/researchers involved in outside consulting or business activities that involve research must establish clear boundaries to differentiate Institute responsibilities from their outside responsibilities.

### **The Institute's teaching and research environment fosters positive learning opportunities for students and preserves free discourse and dissemination of research results.**

- Research conducted by a faculty member/researcher may not involve "works for hire" but must be judged as advancing scholarship and knowledge.
- Preferential access to research results, materials, or products generated from Institute teaching or research activities may not be provided to an outside entity for the personal financial gain of a faculty member/researcher, except in cases in which appropriate licensing arrangements have been developed and approved according to Institute policies.
- When appropriate, research should provide learning opportunities for graduate and/or undergraduate students.
- The Institute will not accept limits placed on the freedom to publish, except for short periods of delay (maximum 90 days with approval of the OSP director) that permit a sponsor to comment, to permit filing of patent applications, or to remove a sponsor's inadvertently included proprietary information.
- Selection of students for participation in a research project should not be inappropriately influenced by the interests of a sponsor, including a company in which the supervising professor may have a significant financial interest.
- Involvement of Institute students, including postdoctoral fellows, in outside professional activities of a faculty member/researcher can be beneficial, but their educational experience should not be diminished or diverted in any way.
- Students, research associates, postdoctoral fellows and research staff should have access to information about sources of funds that support their research.

- Students should not be involved in or employed by any company in which their thesis or dissertation supervisor has a substantial financial interest and, therefore, a potential conflict of interest.
- Faculty members/researchers should not accept research funding in their laboratory from a company in which they have a significant financial interest.

## **EXAMPLES OF ALLOWABLE ACTIVITIES**

The following examples are not considered financial conflicts of interest and are exempt from reporting requirements under the federal financial conflict of interest policies.

- Receiving salary, royalties, honoraria, stipends, or other remuneration from MIT.
- Earning income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities.
- Receiving income from service on advisory committees or review panels for public or nonprofit entities.
- Holding financial interests in business enterprises or entities that, when aggregated for the investigator and the investigator's spouse and dependent children, meets both of the following tests:
  - Is less than \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value,
  - and
  - Is less than a 5% ownership interest in any single entity.

## **EXAMPLES OF NON-ALLOWABLE ACTIVITIES OR THOSE REQUIRING MANAGEMENT PLANS**

- Sponsored projects in which any of the involved investigators (or members of their immediate family) have employment or consulting arrangements or significant financial interests in the sponsor, or with subcontractors, vendors, or collaborators.
- Using Institute resources to conduct research that is sponsored by an entity in which the faculty member/researcher or his/her family member(s) has a significant financial interest.
- Hiring Institute students in consulting activities for a company in which the faculty member/researcher has financial interests. If the student's thesis/dissertation research is supervised by the faculty member, the conflict of interest situation may not be manageable.
- Diverting research opportunities from the Institute to a consulting entity or business in which the faculty/researcher has a financial interest.
- While acting in the context of his/her Institute duties, making professional referrals to or purchasing materials or services from a business in which an academic staff member or family member has a financial interest.
- Serving as president or CEO, or holding another position (such as director of research) that requires involvement in the day-to-day operations of a for-profit company. Such a situation creates an unacceptable conflict of interest which must be reduced or eliminated in order to be manageable.
- Entity (ownership) interest of the faculty member (or members of the immediate family) in a sponsor of the faculty member's research.

## **PROCEDURES FOR DECLARING POTENTIAL CONFLICTS OF INTEREST AND OBTAINING APPROVAL FOR A MANAGEMENT PLAN**

Since 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 NSF, NIH and certain other federal agencies. In addition, an annual disclosure is required to keep all proposal and award disclosures current.

1. Determine if you have a potential financial conflict of interest by reviewing these guidelines and the relevant sections of *Policies and Procedures*. If you have a question about these policies, contact the director, Office of Sponsored Programs.
2. Declare a potential financial conflict of interest by completing the electronic financial conflict of interest disclosure located at [coeus.mit.edu/coeus](http://coeus.mit.edu/coeus)
3. Meet with the Director, Office of Sponsored Programs and the Vice President of Research to develop a Financial Conflict of Interest Management Plan. Once finalized, you will be asked to sign acceptance of the Plan.
4. Each financial Conflict of Interest Plan must include at least an annual reporting to the VPR for which the Conflict of Interest Group will review compliance, and, if necessary, recommend additional compliance measures.
5. In addition, even if the faculty member/researcher has no reportable financial interests at the time the proposal is written/submitted and/or an award is made to the Institute, (s)he has the obligation to complete a financial disclosure statement if any reportable financial interests are subsequently secured.

## **INITIAL REVIEW OF THE FINANCIAL COI MANAGEMENT PLAN**

The investigator must provide to the Director, OSP and VPR the following information for review:

- All relevant financial interests that exceed the threshold of significance as defined in the policy.
- Description of the facts and circumstances regarding the investigator's financial involvement with the sponsoring organization and proposed measures to be taken to ensure that the financial involvement will not affect or impair the conduct of the research.
- Documentation how the interests of the Institute will be maintained in consideration of the investigator's interest in the sponsor.

If it is determined that there is a financial conflict of interest that could affect the design, conduct, or reporting of the research funded or proposed for funding, the Director, OSP and VPR will determine what conditions or restrictions should be imposed to manage or reduce such interests. Any conditions or restrictions must be determined and agreed upon before the expenditure of any funds awarded for the research. Examples of conditions or restrictions that may be imposed include, but are not limited to, the following:

- Public disclosure of significant financial interests in presentations and papers.
- Monitoring of the research by independent reviewers.
- Modification of the research plan and/or disqualification from participation in all or a portion of the research project in question.
- Divestiture of significant financial interest.
- Appointing an impartial person to monitor the use of students.

In some circumstances, it may be determined that the conflict cannot be managed or reduced sufficiently and, therefore, the agreement cannot be approved.

## **CONTINUING REVIEW**

The investigator must provide to the Conflict of Interest Management Group the following information to review at a time established in the Management Plan:

- Description of any additional funding obtained by the investigator for this research.
- Describe articles or other publications that have been generated from this research project and where they have appeared. Provide copies, if required by the Management Plan, of descriptions of financial interests as presented in the publications.
- Describe any research information that has been disclosed to the company and copies of that information.
- Describe any changes of the investigator's and or family members' financial position with the company since the Plan was adopted.

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