

MASSACHUSETTS INSTITUTE OF TECHNOLOGY POLICY AND PROCEDURES ON CONFLICTS OF INTEREST IN RESEARCH

POLICY STATEMENT

A conflict of interest (COI) can be any situation in which financial or other personal considerations have the potential to compromise a researcher's professional judgment and objectivity in the design, conduct or reporting of research. MIT has a responsibility to ensure that its teaching and research environment fosters the generation of new knowledge and positive learning opportunities for students and preserves the integrity of its research enterprise and the public's trust. MIT policy, therefore, requires that MIT officers, faculty, and staff and others acting on its behalf avoid or mitigate real or perceived financial conflicts of interest and ensure that their activities and interests do not conflict with their obligations to MIT or its welfare. The Vice President for Research is responsible for ensuring implementation of this policy.

This Policy is divided into the following sections:

- Policy Statement
 - Definitions
 - Guiding Principles
 - Application of Guiding Principles
 - Disclosure Requirements
 - Review, Evaluation, and Resolution
 - Disclosure to Third Parties
 - Disciplinary Action
 - Record Retention
 - PHS Addendum
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This Policy is intended to assist MIT researchers in applying and complying with MIT's requirements regarding the disclosure, review and reporting of conflicts of interest in research and with the requirements of MIT sponsors. If a sponsor's policy varies significantly from MIT policy, guidance regarding the sponsor's requirements will be provided in an Addendum to this Policy. The PHS Addendum to this Policy sets forth guidance regarding the requirements of the PHS (as defined herein) and certain foundations that have elected to apply the PHS requirements.

Every researcher has an obligation to become familiar with, and abide by, the provisions of this policy. If a situation raising questions of conflict of interest arises, a researcher should discuss the situation with his or her Department, Lab or Center Head, MIT's Conflict of Interest Officer, the Director of the Office of Sponsored Programs, the Conflict of Interest Committee, or the Vice President for Research.

MIT policy requires that researchers disclose certain financial interests, which disclosure enables MIT to determine if a financial interest creates a conflict of interest or the appearance of a conflict of interest. The existence of a conflict or the appearance of one does not imply wrongdoing on anyone's part and does not necessarily mean that a researcher may not retain his or her financial interest and

undertake the affected research. Some conflicts must be eliminated, but often MIT can work with the researcher to manage a conflict or the appearance of a conflict so that the research can continue in a way that minimizes the possibility of bias in the research and preserves the objectivity of the research. Proper management of a conflict depends on full and prompt disclosure.

When in doubt-disclose.

DEFINITIONS

Aggregate means the consolidated total of monies received from a single entity (i.e. through Remuneration, Sponsored Travel, Equity Interests, etc.).

COI Committee means MIT's committee or the individual that advises the Institutional Official with respect to conflict of interest matters.

COI Officer means the MIT staff member responsible for supporting the Institutional Official in implementing this Policy.

Designated Official means either the COI Officer or, in complex cases, the Investigator's Department, Lab, or Center Head; School Dean; or any other member of the senior administration designated by the Institutional Official to review disclosures to determine if there is a relationship between an Investigator's Significant Financial Interest, including for PHS Investigators, Sponsored Travel, and his or her Institutional Responsibilities.

Equity Interests means stock, stock options, warrants, and other existing ownership interests in a commercial entity.

Family means an Investigator's spouse or domestic partner and dependent children.

Financial Conflict of Interest (FCOI) means a Significant Financial Interest and for PHS Investigators, Sponsored Travel, that MIT reasonably determines could directly and significantly affect the design, conduct, or reporting of research.

Institutional Official means the individual within MIT that is ultimately responsible for the review of disclosures of Significant Financial Interests and the management of Financial Conflicts of Interest. MIT's Institutional Official is the Vice President for Research.

Institutional Responsibilities means the Investigator's responsibilities associated with his or her MIT appointment or position, such as research; teaching; administration; conference attendance, research presentations or lectures at other universities or uncompensated publication review; and service on MIT committees.

Investigator means the individual or individuals who are independently responsible for the design, conduct, or reporting of the research project. This is typically, the principal investigator and any co-principal investigator (i.e. the project leadership), though in some cases the principal investigator may determine that others are independently responsible for the project. Some sponsors have specific

requirements for identifying Investigators. See the Office of Sponsored Programs website for more information.

Outside Professional Activities means compensated and uncompensated activities undertaken outside of an Investigator's Institutional Responsibilities.

PHS means the Public Health Service of the U.S. Department of Health and Human Services, including, but not limited to the National Institutes of Health (NIH), the Administration for Children and Families, Administration on Aging, Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Federal Occupational Health, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, and Substance Abuse and Mental Health Services Administration. The most current list can be found at <http://www.hhs.gov/open/contacts/index.html#od>

Related Entity means any domestic or foreign, public or private, for profit, non-profit or governmental organization in which the Investigator, alone or in combination with his or her Family, holds a Significant Financial Interest.

Remuneration includes salary and payments for services, such as consulting fees, honoraria or paid authorship, and cash or in kind gifts from entities for which you provide services and, for PHS Investigators, Sponsored Travel.

Significant Financial Interest (SFI) means a financial interest that meets any of the criteria for significance set forth below and is received or held:

1. by an Investigator; or
2. by an Investigator and members of his or her Family; or
3. solely by members of the Investigator's Family, but only if the financial interest could reasonably appear to be related to the Investigator's Institutional Responsibilities.

A financial interest is deemed to be significant if:

- a. the Aggregate value of Remuneration and Equity Interests in lieu of payment, received from a **U.S. or foreign publicly traded** entity during the 12 month period preceding the disclosure exceeds \$5,000; or
- b. the Aggregate value of Equity Interests in a **U.S. or foreign publicly traded** entity exceeds \$5,000 and the entity is sponsoring any of the Investigator's research; or
- c. the Aggregate value of Equity Interests in a **U.S. or foreign publicly traded** entity exceeds \$100,000 and the entity's business, or any portion thereof, reasonably appears to be related to any of the Investigator's Institutional Responsibilities; or
- d. the Aggregate value of Remuneration received from a **U.S. or foreign non-publicly traded entity or non-profit institution** during the 12 month period preceding the disclosure exceeds \$5,000; or

- e. any Equity Interest is held in a **U.S. or foreign non-publicly traded** entity; or
- f. the Aggregate value of Remuneration received from a **foreign governmental organization** during the 12 month period preceding the disclosure exceeds \$5,000; or
- g. the Aggregate value of income related to intellectual property rights and interests paid by an entity other than MIT exceeds \$5,000.

Significant Financial Interest does NOT include:

1. Remuneration from MIT; (including salary and royalty payments); and
2. Remuneration paid to an Investigator's Family by any entity that would not reasonably appear to be related to the Investigator's Institutional Responsibilities; and
3. Remuneration from authorship of academic or scholarly works, regardless of the source; and
4. Remuneration from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for U.S. Federal, state, or local governmental agencies; U.S. institutes of higher education (e.g. Whitehead Institute and Broad Institute); U.S. research institutions affiliated with U.S. institutions of higher education, U.S. academic teaching hospitals, and U.S. medical centers; and
5. Equity Interests in or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions for these vehicles.

Sponsored Travel (applies only to PHS Investigators) means (a) travel expenses paid to an Investigator or travel paid on an Investigator's behalf, by a single entity in any 12-month period and (b) travel reimbursed to or paid on behalf of an Investigator's Family by a single entity in any 12-month period **ONLY** if such travel reasonably appears to be related to the Investigator's Institutional Responsibilities. See the PHS Addendum for more information.

GUIDING PRINCIPLES

A number of guiding principles inform our approach to identifying and addressing Financial Conflicts of Interest. These include:

1. An Investigator's first and primary responsibility is to support and advance MIT's mission, rather than to advance his or her personal financial interests.
2. Research must be undertaken to advance scholarship and new knowledge and not an Investigator's or the Investigator's Family's personal financial interest.
3. Financial Conflicts of Interest must be identified and either managed or eliminated.

4. Disclosure of Significant Financial Interests and Outside Professional Activities is integral to identification of Financial Conflicts of Interest.
5. An Investigator must not attempt to influence the activities of colleagues and subordinates with the intent of enhancing the Investigator's or the Investigator's Family's financial interests.
6. Research results must not be withheld or provided on a preferential basis for the benefit of an Investigator's or the Investigator's Family's financial interest.
7. MIT's resources, names and trademarks may not be used for personal benefit.
8. Investigators must disclose any actual Financial Conflicts of Interests and any Significant Financial Interests that may appear to give rise to a Financial Conflict of Interest to students and staff who participate in their research.
9. Extra scrutiny must be given to potential Financial Conflicts of Interest in research involving human subjects.
10. An Investigator may not supervise directly or indirectly any member of his or her Family nor may an Investigator assume the role of advocate or judge regarding a Family member's employment, salary, or promotion.

APPLICATION OF GUIDING PRINCIPLES

In an effort to ensure that MIT manages or eliminates Financial Conflicts of Interests, MIT has defined various actions or activities that either are not permitted or require prior approval.

Investigators may not:

1. accept research sponsorship or gifts, in support of the Investigator's Institutional Responsibilities from a for-profit privately-held Related Entity;
2. subcontract to a for-profit privately-held Related Entity;
3. negotiate with MIT on behalf of a Related Entity, or negotiate with the Related Entity on behalf of MIT;
4. involve a student for whom the Investigator is a thesis supervisor in the Investigator's Outside Professional Activities;
5. divert research opportunities to a Related Entity, which are more appropriately undertaken at MIT, such as research sponsorship or other projects;
6. promote the use of products or services of a Related Entity in the course of the Investigator's Institutional Responsibilities;

7. engage in research involving human subjects that could reasonably be expected to affect the financial condition of a Related Entity.

An Investigator must obtain the prior written approval of the Investigator's Department, Lab, or Center Head (e.g. Designated Official), and in appropriate cases, enter into a management plan, before the Investigator:

1. accepts research sponsorship or gifts, in support of the Investigator's Institutional Responsibilities from a publicly-held or non-profit Related Entity;
2. accepts an in-kind gift from a publicly-held or non-profit Related Entity for use in his or her Institutional Responsibilities;
3. accepts research sponsorship from a Related Entity from which the Investigator receives Remuneration (for example, it may be permissible for an Investigator to receive research sponsorship from a Related Entity for whom the Investigator consults if the Designated Official determines that the consulting scope of work and the research scope of work are separate and distinct);
4. purchases goods or services from a Related Entity (for example, the Designated Official, in collaboration with Procurement, could determine that the goods and services are not commercially available from another provider);
5. provide goods, services, or access to facilities to a Related Entity (for example, MIT may determine to make certain unique facilities available for use by outside entities, in which case a Related Entity could be entitled to use the facilities on the same basis as other entities);
6. involves a student for whom the Investigator is not a thesis supervisor in his or her Outside Professional Activities, as an employee or consultant or in any other capacity (such involvement may be beneficial for the student, but the student's educational experience must not be diminished or diverted);
7. involves staff in the Investigator's Related Entity's activities as contemplated by MIT Policies and Procedures Sections 4.5.3;
8. request an appointment for an individual from a Related Entity to participate in research at MIT.

DISCLOSURE REQUIREMENTS

Full and prompt disclosure of Significant Financial Interests (including, for PHS Investigators, Sponsored Travel) is critical to MIT's ability to identify, manage, and eliminate Financial Conflicts of Interest. Investigators must describe a Related Entity's business focus, their work or role with the Related Entity and any relationship to their Institutional Responsibilities. *Please note: All MIT faculty and staff must also disclose certain information with respect to conflicts of interest in their annual report on Outside Professional Activities and Interests.*

1. **Creating a COI disclosure.** An Investigator must create a COI disclosure in Coeus, which discloses the Investigator's SFIs and how they relate to the Investigator's Institutional Responsibilities. Once approved, the disclosure becomes a master disclosure, which maintains an ongoing record of the Investigator's proposals, awards, SFIs, all approved disclosures and, for PHS Investigators, Sponsored Travel, for as long as the Investigator remains at MIT. See coi.mit.edu for more details.

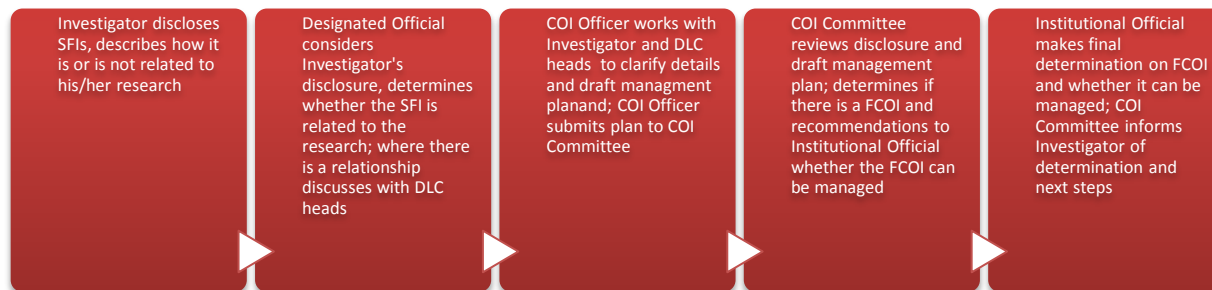
When an Investigator joins a research project already in progress, an Investigator must disclose to MIT his or her SFIs prior to the Investigator commencing participation in the research project.

2. **Maintaining a master disclosure.**
 - a. An Investigator must disclose to MIT any new SFI within a reasonable period (generally 90 days) following the date on which the SFI is acquired or arises. PHS funded Investigators must disclose any new SFI within 30 days following the date on which the SFI is acquired or arises and any Sponsored Travel within 30 days after completing the travel.
 - b. Disclosures must be updated at least every 12 months and Investigators will be notified of the expiration date via email.

REVIEW, EVALUATION, AND RESOLUTION

The Designated Official will determine if the Significant Financial Interest identified in a COI disclosure is related to the Investigator's Institutional Responsibilities. The Designated Official will be the COI Officer, the Department, Lab, or Center Head, or another member of the senior administration, depending on the circumstances. The COI Officer will review all disclosures, and when possible, make the determination. In complex cases, the Department, Lab, or Center Head or member of the senior administration will make the determination. If the Designated Official determines that the Significant Financial Interest is related to the Investigator's Research, the disclosure will be submitted to the COI Committee for determination as to whether the Significant Financial Interest constitutes a Financial Conflict of Interest or the appearance of a Financial Conflict of Interest and, if so, whether it can be managed. The COI Committee will submit a recommendation to the Institutional Official. The Institutional Official will then undertake his or her own evaluation and will determine whether the Investigator will be required to eliminate or manage the Financial Conflict of Interest, as appropriate. The Institutional Official may suspend all relevant activities until the Financial Conflict of Interest is resolved.

COI DISCLOSURE REVIEW PROCESS

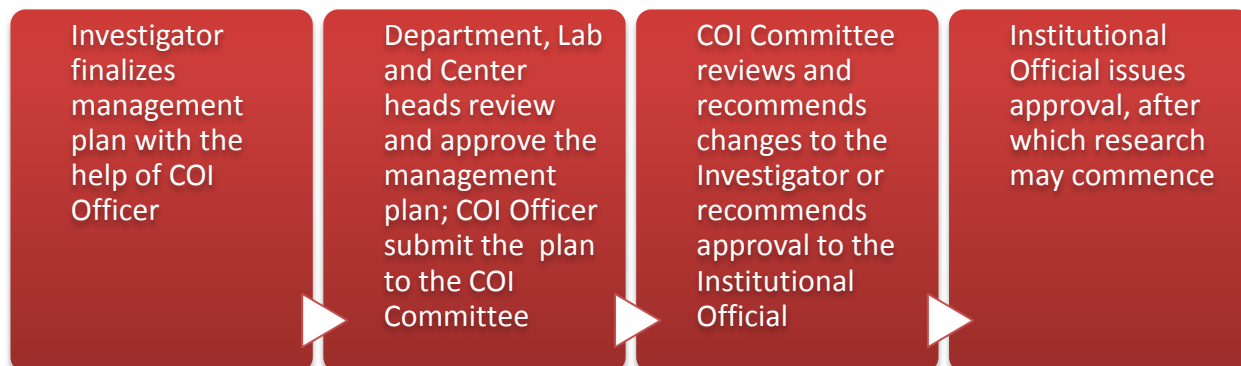


Elimination. A Financial Conflict of Interest may be eliminated by divestiture of Equity Interests; termination of the relationship that gives rise to the Significant Financial Interest (such as consulting); abandoning the proposal; terminating the sponsored project; and similar measures.

Management. If the Investigator does not want to eliminate a Financial Conflict of Interest or the appearance of a Financial Conflict of Interest and the Institutional Official determines that it can be managed, the Investigator must develop a written management plan. The COI Officer will assist the Investigator in developing the plan.

Each management plan must be approved and signed by the Investigator, his or her Department Head and, if the research will be carried out in a Laboratory or Center, the Laboratory or Center Head. Where the Investigator is the Department, Lab or Center Head, the plan must be co-signed by the Dean with oversight responsibility for the unit. The management plan will then be submitted to the COI Committee for comment and approval. Once the COI Committee has approved the management plan, the plan will be submitted to the Institutional Official for approval. The Investigator may not commence or participate in the research that gives rise to the Financial Conflict of Interest or the appearance thereof until all approvals are obtained. Management plans are maintained by the COI Officer and are updated annually.

FINANCIAL CONFLICT OF INTEREST MANAGEMENT PROCESS



The goals of a management plan are to ensure open and timely dissemination of research results, protect students, and preserve the objectivity of the research. Examples of conditions or restrictions that may be imposed by a management plan include:

1. public disclosure of Significant Financial Interests (e.g., when presenting or publishing Research);
2. disclosure of Financial Conflicts of Interest directly to participants in human subjects research;
3. appointment of an independent monitor or oversight committee capable of taking measures to protect the design, conduct, and reporting of research against bias;
4. modification of the research plan;
5. change of personnel or personnel responsibilities or disqualification of personnel from participation in all or a portion of the Research;
6. reduction or gradual elimination of the Significant Financial Interest (e.g., sale of an Equity Interest);
7. severance of the relationship that is the source of the Significant Financial Interest;
8. expedited dissemination of research results so that the Related Entity does not receive preferential access; and
9. monitoring of involvement of students and postdoctoral appointees by independent reviewers or oversight committees.

The management plan template is available from the COI Officer or may be downloaded from <http://coi.mit.edu/management-plan>.

DISCLOSURE TO THIRD PARTIES

MIT may be required, by law or by conditions imposed by a sponsor, to report a FCOI and also any failure to report a FCOI, to the affected project sponsors.

DISCIPLINARY ACTION

In the event an Investigator fails to comply with this Policy, the Institutional Official may suspend all relevant activities of the Investigator and take disciplinary or other administrative action pursuant to MIT policy. The responsibility for initiating disciplinary action normally resides with the faculty member's Department Head or Dean or the Institutional Official. Disciplinary actions may include, but are not limited to, a reprimand, oral or written, private or public; a period of suspension with or without pay; a reduction in salary; removal of privileges; or dismissal in accordance with MIT Policies and Procedures.

RECORD RETENTION

The COI Officer will retain all disclosures, conflict management plans, and related documents for a period of at least three years following submission of the final expenditure report for the applicable project to

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the sponsor of the research that gives rise to the Financial Conflict of Interest, unless any litigation, claim or negotiation, audit, or other action involving the records is commenced before expiration of the three-year period, in which case, records will be retained until completion of the action and resolution of all issues.

PHS ADDENDUM TO MIT POLICY ON CONFLICTS OF INTEREST IN RESEARCH

This PHS Addendum implements the requirements of certain federal regulations, specifically 42 CFR 50 and 45 CFR 94, and applies to all projects funded, directly or indirectly through a subaward from another organization, by the PHS other than SBIR or STTR awards. This PHS Addendum supplements MIT's Policy on Conflicts of Interest in Research. PHS regulations differ, in some respects, from MIT's Policy. It is imperative, therefore, that every MIT Investigator that accepts PHS funding, whether directly or indirectly, becomes familiar with, and abides by, the provisions of this PHS Addendum.

This policy also applies to projects funded by certain foundations that have elected to apply the PHS standards and requirements relating to financial conflicts of interest. A list of these foundations is available at <http://coi.mit.edu/sponsor-specific-guidelines/foundations>.

IDENTIFYING INVESTIGATORS

Investigator means the individual or individuals who are independently responsible for the design, conduct, or reporting of the research project. This is typically the principal investigator and any co-principal investigator (i.e. the project leadership), though in some cases the principal investigator may determine that others are independently responsible for the project. While a title alone cannot determine who is an Investigator, postdoctoral appointees and graduate students are rarely considered independently responsible for a project. For NIH projects, the individuals identified in the proposal as "key personnel" may be Investigators.

A matrix designed to assist Principal Investigators in identifying Investigators can be found at <http://coi.mit.edu/sponsor-specific-guidelines/national-institutes-health-nih/who-investigator>.

SPONSORED TRAVEL

PHS requires that Sponsored Travel be included in the determination of whether the Aggregate value of an Investigator's financial interests rises to the level of a Significant Financial Interest. Sponsored Travel includes (a) travel expenses paid to an Investigator or travel paid on an Investigator's behalf, by a single entity in any 12-month period and (b) travel reimbursed to or paid on behalf of an Investigator's Family by a single entity in any 12-month period, ONLY if such travel reasonably appears to be related to the Investigator's Institutional Responsibilities.

NIH states that looking back over the previous twelve-month period provides baseline information that allows MIT to take into account whether Investigators have an ongoing financial relationship with an entity providing a payment or reimbursement or whether the payment or reimbursement was limited in duration.

In order to ensure compliance with PHS regulations, therefore, an Investigator must update his or her master COI disclosure to include Sponsored Travel if the Sponsored Travel equals or exceeds \$5,000, alone or in combination with other Remuneration and Equity Interests:

- at the time of submission of a proposal to PHS, looking back over the previous 12 months;

- thereafter, within 30 days following reimbursement or within 30 days following the completion of a trip, if the PHS Investigator has an active award or pending proposal with a PHS agency.

An Investigator need not disclose Sponsored Travel paid for or reimbursed by:

- MIT (e.g. paid from MIT funds or from sponsored awards funds managed at MIT)
- U.S. Federal, state or local governmental agencies
- U.S. Institutes of higher education
- U.S. Research institutions affiliated with institutions of higher education
- U.S. Academic teaching hospitals and medical centers

The disclosure must include at a minimum, the purpose, cost of the trip (estimate if unknown), the identity of the organization or entity funding the travel, the destination, the duration of the trip (usually days), and the relationship between the trip and the PHS Investigator's proposals and awards. The Designated Official may request additional information to determine whether the Sponsored Travel is related to the Investigator's Institutional Responsibilities in accordance with the Review, Evaluation and Resolution section of this policy.

TRAINING

MIT must provide training regarding MIT's Policy and the regulations to Investigators. PHS Investigators must complete the training prior to MIT charging effort to the PHS award, and at least every four years thereafter. Investigators must also complete training within a period of time determined by the Institutional Official if (i) this PHS Addendum is substantively amended in a manner that affects the requirements of Investigators or (ii) MIT determines that the Investigator has not complied with this PHS Addendum or with a management plan related to his or her research.

Training will be provided through the Collaborative Institutional Training Initiative (CITI). More information can be found at <http://coi.mit.edu/sponsor-specific-guidelines/national-institutes-health-nih/training-requirements-phs-investigators>.

REPORTING TO PHS

PHS agency funded Investigators are required to disclose an SFI within 30 days of identifying the SFI. MIT shall, within 60 days, review the disclosure, determine its relatedness, determine if it is an FCOI and if so, implement a management plan. Within 60 days of determining whether an SFI is an FCOI, MIT must report the FCOI details, including details of the management plan, to the PHS funding agency.

The PHS regulations require MIT to provide the following information regarding Financial Conflicts of Interest:

1. if the Financial Conflict of Interest existed prior to award, prior to expenditure of funds;
2. if the Financial Conflict of Interest arises during the term of the award, within 60 days of determining whether a Significant Financial Interest is a FCOI (see Disclosure Requirements above);
3. as part of the annual progress report on the Research;
4. as part of any requests for an extension of the award; and

5. following a retrospective review as discussed in more detail under RETROSPECTIVE REVIEW below.

Each report to PHS must include sufficient information to enable PHS to understand the nature and extent of the financial conflict and to assess the appropriateness of the management plan. The required information includes:

1. project number;
2. Principal Investigator or Contact Principal Investigator if there are multiple Principal Investigators on the project;
3. name of the Investigator with the Financial Conflict of Interest;
4. name of the entity with which the Investigator has a Financial Conflict of Interest;
5. nature of the Significant Financial Interest (e.g., Equity, consulting fees, travel reimbursement, honorarium);
6. value of the Significant Financial Interest, which value may be expressed as being within a range (\$0– \$4,999; \$5,000–\$9,999; \$10,000– \$19,999; amounts between \$20,000– \$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000) or, if the value of the interest cannot be readily determined through reference to public prices or other reasonable measures of fair market value, a statement confirming that fact;
7. a description of the relationship of the Significant Financial Interest to the PHS-funded research and the basis for MIT's determination that the Significant Financial Interest conflicts with the research; and
8. a description of the key elements of the management plan, including:
 - a. the role and principal duties of the conflicted Investigator in the research;
 - b. the conditions of the management plan;
 - c. how the management plan is designed to safeguard the objectivity of the research;
 - d. confirmation of the Investigator's agreement to the management plan;
 - e. how the management plan will be monitored to ensure Investigator compliance; and
 - f. other relevant information.

PUBLIC ACCESSIBILITY

PHS requires MIT to make information regarding Financial Conflict of Interests reported to PHS, available to the public upon request. The minimum amount of information that must be made available includes the following:

1. Investigator's name;
2. Investigator's title and role with respect to the research;
3. name of the entity in which the Significant Financial Interest is held or from which it is received;
4. nature of the Significant Financial Interest; and
5. approximate value of the Significant Financial Interest, which value may be expressed as being within a range as described above or if the value of the interest cannot be readily determined through reference to public prices or other reasonable measures of fair market value, a statement confirming that fact.

MIT may also disclose information regarding the management of the Financial Conflict of Interest.

Instructions for requesting information about a reported Financial Conflict of Interest can be found at <http://coi.mit.edu/contact-us/fcoi-public-information-request-form>.

SUBAWARDS ISSUED BY MIT UNDER PHS FUNDED PRIME AWARDS

When MIT issues a subaward to another organization to carry out a portion of a PHS funded project, the subawardee must comply with the PHS conflict of interest regulations. MIT, therefore, will only issue subawards under PHS funded awards to institutions that have financial conflict of interest policies that comply with the PHS regulations.

If a subawardee Investigator has a Financial Conflict of Interest, MIT is responsible for reporting the Financial Conflict of Interest to the PHS on behalf of the subawardee. As a result, subawardees must report Financial Conflicts of Interest to MIT within 30 days of determining whether there is a Financial Conflict of Interest so that MIT may report it to the PHS in a timely manner. In addition, MIT is required by PHS to make information regarding subawardee Financial Conflicts of Interest available to the public. MIT will report subawardee Financial Conflicts of Interest using the same method it uses to disclose its own Financial Conflicts of Interest, and will notify the subawardee of any requests for information. Questions regarding the specifics of subawardee Financial Conflicts of Interest are directed to the subawardee.

SUBAWARDS ISSUED TO MIT UNDER PHS FUNDED PRIME AWARDS

When MIT makes a proposal for or receives a subaward from another organization to carry out a portion of a PHS funded project, MIT must comply with the PHS regulations regarding conflicts of interest. MIT's Policy and this PHS Addendum apply to these proposals and awards rather than the policies of the subawarding organization. MIT provides reports of Financial Conflicts of Interest to the subawarding organization for reporting to PHS as specified in the PHS regulations. Reports are provided in the same form and format as MIT uses in connection with its direct awards from PHS. The subawarding organization is also responsible for the public accessibility reporting (see above). The subawarding organization may choose to do so either by posting MIT's report to a publicly available website or responding to written requests within 5 business days.

INVESTIGATOR NON-COMPLIANCE - RETROSPECTIVE REVIEW

In cases where a Financial Conflict of Interest is not identified or managed in a timely manner, including due to 1) failure by the Investigator to disclose a Significant Financial Interest that is determined by the Institution to constitute a Financial Conflict of Interest; 2) failure by MIT to review or manage such a Financial Conflict of Interest; or 3) failure by the Investigator to comply with a Financial Conflict of Interest management plan, MIT must, within 120 days of its determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded research to determine whether the design, conduct, or reporting of the PHS-funded research, or any portion thereof, conducted during the period of noncompliance, was biased. Retrospective reviews will be conducted by the Office of the General Counsel or other MIT personnel, as determined by the Conflict of Interest Committee.

MIT is required to document the retrospective review and report detailed findings to PHS, including at least the following key elements:

1. project number;
2. project title;
3. Principal Investigator or contact Principal Investigator if there are multiple Principal Investigators on the project;
4. name of the Investigator with the Financial Conflict of Interest;
5. name of the Entity with which the Investigator has a Financial Conflict of Interest;
6. reason(s) for the retrospective review;
7. detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
8. findings of the review; and
9. conclusions of the review.

Based on the results of the retrospective review, MIT will update the previously submitted Financial Conflict of Interest report, if appropriate, specifying the actions that will be taken to manage the Financial Conflict of Interest. If bias is found, MIT must notify PHS promptly and submit a mitigation report. The mitigation report must include, at a minimum:

1. the elements documented in the retrospective review above;
2. a description of the impact of the bias on the research; and
3. MIT's plan of action or the actions taken to eliminate or mitigate the effect of the bias (e.g., extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research is salvageable).

Thereafter, MIT will submit Financial Conflict of Interest reports annually, as specified under the PHS regulations. Depending on the nature of the Financial Conflict of Interest, MIT may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research between the date that the Financial Conflict of Interest or the Investigator's noncompliance is determined and the completion of MIT's retrospective review.

RECORD RETENTION

The COI Officer will retain all disclosures, conflict management plans, and related documents for a period of at least three years following submission of the final expenditure report for the applicable project to the PHS or the prime PHS awardee, unless any litigation, claim or negotiation, audit, or other action involving the records is commenced before expiration of the three-year period, in which case, records will be retained until completion of the action and resolution of all issues.