

# A Shared Responsibility

## *Report of the Committee on Managing Potential Conflicts of Interest in Research*

### **Overview: Appointment of Committees on Managing Potential Conflicts of Interest in Research and MIT Technology Transfer in the 21<sup>st</sup> Century**

MIT has long-standing policies and procedures designed to preserve the integrity of its research enterprise and foster technology transfer. These policies are well developed and reflect a deep commitment to preserving the Institute's fundamental academic values and principles. However, in recent years the complexity of the research enterprise has increased, the scope and nature of intellectual property have undergone profound changes, and increasing numbers of faculty, research staff, postdocs, graduate students, and even undergraduates are involved in commercial activities. Therefore, it is both timely and appropriate for MIT to undertake a comprehensive review of its principles, policies, and procedures related to potential conflicts of interest and to technology transfer. To this end, *two ad-hoc faculty committees* were appointed by the Provost dealing with the interrelated issues in this area. The membership and the extended charges to these two committees appear in the Appendix. The membership and the charge to the Committee on Managing Potential Conflicts of Interest in Research are summarized below.

### **Charge: Managing Potential Conflicts of Interest in Research**

This committee will review the kinds of individual and institutional relationships that could give rise to the perception or reality of conflicts of interest; assess regulations, legal requirements, and best practices at other major institutions; and examine written and practiced policies and procedures related to conflicts of interest. They will also recommend any changes to strengthen our policies and procedures; review mechanisms for monitoring and reporting conflicts of interest; examine relevant procedures within current research groups; and recommend programs for ongoing education and information exchange regarding conflict of interest in research.

Faculty appointed to this committee are:

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## Summary of Observations and Recommendations

MIT has been, and remains, a world leader in engagement with government and industry to tackle the pressing problems of our society. MIT is a values-based institution with an abiding commitment to integrity, excellence and public service. MIT has been a leader in the effective transfer of technology from the Institute to industry. And MIT is a place that couples well to the real world, making tangible and practical contributions to the economy and the welfare of the nation and the world. These changes give rise to new opportunities, new sources of competition, and greater variety and complexity. They also give rise to concern about conflicts of interest or the appearance of conflicts of interest in research.

Public support for the funding of research is based in part on the perception that universities and their faculty act primarily in the public interest. Public reaction to reports of conflict of interest in research, especially in areas involving research on human subjects, has undermined this support and caused considerable concern among members of Congress and leaders of the government agencies that support research. Federal regulations to deal with these concerns are in a constant state of revision and have already significantly affected the research environment at MIT.

MIT has had long-standing policies governing the reporting and managing of potential conflicts of interest. The primary bases for these policies are:

1. We have a responsibility to ensure that the education of our students is not affected by the financial and other external interests of our faculty or staff.
2. The principal loyalty of our faculty and staff in both time and energy must be devoted to MIT.
3. Research directions, goals of the project, and evaluation and sharing of results, should not be affected by the external financial interests of individual faculty or staff.
4. As a non-profit institution, MIT must ensure that faculty (and other members of the academic community) do not obtain more than incidental private financial benefit from the *significant* use of MIT resources.
5. We have a responsibility to ensure that the external financial and business relationships of MIT and its officials do not compromise MIT's research, teaching, outreach or other activities.

While we believe that MIT's policies on conflict of interest are basically sound, we find that the various procedures used to identify potential individual conflict of interest lack completeness and clarity. This is true particularly in the area of disclosure. We recommend enhanced disclosure in several important areas dealing with our responsibility to students, the outside relationships of our faculty and staff and the potential for significant use of MIT facilities on behalf of such outside interests. We also found some ambiguity in several of our current policies and recommend clarification. We have outlined responsibilities for Department Heads within the framework of current policies. We also recommend that the Provost establish a *Committee on Conflict of*

***Interest in Research*** to provide continuing independent advice and oversight on actions taken and policies enacted to identify, avoid and/or manage conflict of interest in sponsored research.

While rules, guideline and procedures are necessary for orderly conduct as well as clarity of purpose, the most fundamental premise, the foundation on which we behave and work with others, is trust. Trust between individuals and between the institution and those who both govern and work within it must be a core value that holds us together. Rules provide guidelines but we must believe that all will abide by them both in fact and spirit. It is this trust in others that allows us to proceed.

**We here summarize the various recommendations that appear in our report.**

### **Outside Professional Activities (OPA) reporting**

- 1. We recommend the use of the new faculty OPA form (that was initiated for the 2008-09 reporting cycle) and its continued update going forward.**
- 2. Substantial new activities require prior notification and approval of the Department Head whether based on the expenditure of time anticipated or issues raised regarding personal conflict of interest and/or involvement of students, postdoctoral staff, use of MIT facilities or research staff.**
- 3. In situations in which faculty hold a dual appointment, the OPA form should be submitted to both Department Heads.**
- 4. The current staff OPA form is relatively brief, and should be improved and expanded, similar to what has been done so far with the faculty form, in order to clarify staff reporting and disclosure requirements.**
- 5. We recommend clarification and communication of MIT policy dealing with allowable external activities for each of the staff categories, including clarification of policies governing part-time or uncompensated staff appointments.**
- 6. The OPA form should also require disclosure of significant use of MIT facilities by or on-behalf-of outside entities related to the outside professional activities of the faculty and staff.**
- 7. We recommend that MIT establish a mechanism to ensure that Department Heads have the knowledge and the tools to fulfill their responsibilities.**

### **Visitors and Affiliates**

- 1. The appointment forms for Visiting and Affiliated Faculty and Research Staff should include questions about outside relationships with MIT faculty, students and staff.**
- 2. Visiting and Affiliated Faculty and Research Staff should be required to submit an OPA report detailing their outside relationships with MIT faculty and their use of MIT staff, students and facilities.**

## **Disclosure and resolution as part of the research proposal submission process**

- 1. OSP should develop a more specific set of questions to construct an internal cover form for proposal submission to obtain disclosure from faculty to OSP regarding any potential conflict of interest related to a specific proposal. This form would be used by the Department Head or Laboratory Director to approve the proposal going forward.**
- 2. If during the proposal submission process, the Vice President for Research determines a management plan is needed to mitigate a potential conflict of interest in the research the Department Head, as well as the Laboratory/Center Director as appropriate, should be involved in its development, reflecting their joint responsibility for the research program, the faculty and research staff, and the education of students.**
- 3. We recommend that the Provost establish a *Committee on Conflict of Interest in Research* to provide continuing independent advice and oversight on actions taken and policies enacted to identify, avoid and/or manage conflict of interest in sponsored research.**

## **Protecting students, post-docs, etc**

- 1. Students should not be asked to sign Non-Disclosure Agreements (NDAs) in connection with their participation in faculty research projects, unless the NDA has been explicitly approved by either OSP or TLO. Student signing of such NDAs also must be approved by the Department Head.**
- 2. We recommend that MIT review the issue of NDAs in connection with the work of the Committee on MIT Technology Transfer in the 21<sup>st</sup> Century.**
- 3. We recommend that all agreements signed by students acknowledging the confidential nature of information in their research be approved by Department Heads.**
- 4. The policy on consulting privileges of postdocs and any involvement in the outside activities of their faculty supervisors needs clarification with respect to the extent and character of their consulting privileges and their allowed activities.**
- 5. We urge that any request for part-time postdoctoral appointments receive the highest level of scrutiny from Department Heads, Laboratory Directors as appropriate, Deans and possibly the Vice President for Research.**

## **Human subjects research**

- 1. MIT should institute a policy of full financial disclosure for faculty engaged in human subjects research in cases such as research involving evaluation of a product or drug for human use.**

**2. All MIT faculty should remain under the guidance of MIT policies both in their teaching and in their research in the area of human subjects research, regardless of where the research is conducted.**

### **Institutional conflicts**

**MIT should review its policies, practices and understandings relating to institutional conflicts of interest and consolidate them into a single policy framework.**

## **REPORT**

### **POINT OF VIEW**

MIT has been, and remains, a world leader in engagement with government and industry to tackle the pressing problems of our society. MIT is a values-based institution with an abiding commitment to integrity, excellence and public service. MIT has been a leader in the effective transfer of technology from the Institute to industry. And MIT is a place that couples well to the real world, making tangible and practical contributions to the economy and the welfare of the nation and the world. These changes give rise to new opportunities, new sources of competition, and greater variety and complexity. They also give rise to concern about conflicts of interest or the appearance of conflicts of interest in research.

Public support for the funding of research is based in part on the perception that universities and their faculty act primarily in the public interest. Public reaction to reports of conflict of interest in research, especially in areas involving research on human subjects, has undermined this support and caused considerable concern among members of Congress and leaders of the government agencies that support research. Federal regulations to deal with these concerns are in a constant state of revision and have already significantly affected the research environment at MIT.

MIT has had long-standing policies governing the reporting and managing of potential conflicts of interest. We believe that the principles underlying these policies are basically sound. However the policy statements themselves are often ambiguous. The application of these policies in complex situations, as well as the underlying reasons for them, are not well understood or perhaps accepted by all. Recent national events have highlighted the abuses that can occur when **individual** conflicts of interest lead to abuse with respect to the education of students, relationships with faculty colleagues, reporting, interpretation and application of research results and formulation of research programs and goals. More recently the spotlight has fallen upon **institutional** conflicts of interest, in which the financial interests of an institution or senior administrators lead to abuses. We deal with both issues in this report and give appropriate definitions and examples.

### **Individual Conflict of Interest**

An **individual** conflict of interest exists when an individual (or his or her immediate family) has a financial or other personal interest that affects or has the potential to affect the individual's conduct of his or her Institute activities. Conflicts of interest can arise naturally from an individual's

engagement with the world outside the Institute, and the mere existence of a conflict of interest does not necessarily imply wrongdoing on anyone's part. ***When conflicts of interest do arise, however, they must be recognized, disclosed and either eliminated or properly managed.***

The following list of examples, while not comprehensive, is illustrative of situations which may lead to an indirect or direct potential conflict of interest:

*Deriving Personal Gain from Outside Interests:*

- Entering into a research contract, subcontracting or purchasing relationship with a company in which the faculty or staff member, or a member of her/his immediate family, has a financial or other interest.
- Directing the faculty member's sponsored research program to serve the research or development needs of a private firm in which the faculty member has a financial or other interest.
- Influencing the purchase of equipment or materials for the Institute from a company in which the faculty or staff member has a financial or other interest.
- Accepting significant gifts or special favors for personal gain from private organizations with which the Institute does business.
- Participating directly in the negotiation of a licensing agreement for the development of intellectual property, generated as a result of MIT research, with a company in which the faculty or staff member has a financial or other interest.

*Use of MIT Personnel, Resources or Assets:*

- Using MIT students or staff to carry out work on for a company in which the supervising faculty or staff member has a financial interest.
- Unauthorized and non-reimbursed use of Institute resources or facilities by a faculty member or an employee of a private concern to benefit a private concern in which the faculty or staff member has a financial or other interest
- Arranging an appointment as a Research Affiliate for an individual related to an outside financial interest of a faculty or staff member. Depending upon the circumstance, such an individual might have access to an MIT office, research facilities, staff and students, as well as to research activities themselves that support the outside financial interests of the faculty member.
- While acting in the context of his/her Institute duties, making professional referrals to or purchasing materials or services from a business in which the individual has a significant financial interest.

*Use of Information:*

- Using for personal gain, or other unauthorized purposes, privileged information acquired as a result of the faculty or staff member's MIT-supported activities; such information might include knowledge of forthcoming developments requiring contractor or sub-contractor selection, licensing of intellectual property, bulk purchases, etc.

- Unreasonably delaying publication of research results (e.g., thesis research) or premature announcement of research results to secure personal gain, including providing advance notice to a company of research results prior to publication.

*Conflict of Commitment:*

- Undertaking external consulting, professional or other activities which, by virtue of their time commitment, prevent the faculty or staff member from fulfilling her/his obligations to MIT.
- Involvement in external organizations which bring a faculty or staff member into a position of divided loyalty between the mission of the Institute and the interests of the external organization.
- Membership on a company board. This requires the assumption of fiduciary responsibility in which the Board member pledges to represent the interests of the shareholders. This inherently leads to potential conflicts if the company engages in any research or business activity with MIT that involves the Board member.

*Involvement in Appointment Processes:*

- Participating in the evaluation, appointment, promotion or hiring of a person with whom the faculty or staff member has a financial, marital, familial or sexual relationship.
- Appointing employees of a company in which the researcher or the researcher's family has a financial relationship to the faculty member's research staff at MIT.

Conflicts may also exist with respect to matters with both financial and non-financial implications, such as decisions about the use of Institute equipment and facilities and the negotiation of research agreements and license agreements; and particularly with respect to the conduct of research, the protection of human research subjects, and the treatment of students and faculty colleagues.

An individual's economic interests include his or her interest in obtaining, maintaining or increasing the value of relationships such as employment, independent contractor or consultant; management positions, board memberships and other fiduciary relationships with for-profit organizations; ownership of stock or other securities and other financial interests such as loans or royalties; and any other activity from which the individual receives or expects to receive remuneration. They also include such interests on the part of the individual's spouse (or spousal equivalent) and his or her financially dependent children.

Association of MIT's image or name with commercial interests in the public eye may lead to a conflict of interest. In the course of consulting or research, a faculty member may provide a professional evaluation of products or services, based on evidence. However, publicly advertised endorsement of commercial products or services is not, in general, consonant with the independence and objectivity expected of faculty members. In the conduct of their outside professional activities, faculty members should be careful to avoid identifying the Institute with opinions or conclusions in public or private reports that support the outside financial interests of the faculty member.

External economic interests create conflicts of interest when they provide an incentive to the individual to affect an Institute decision or other activity (for example, because of the possibility of personal gain), and when the individual has the opportunity to affect the Institute decision or other activity (for example, because he or she is the decision-maker or the principal investigator for a research project).

Conflicts of interest related to research involving human subjects pose special concerns. The Institute and its researchers have ethical obligations to honor the rights and protect the safety of persons who participate in research conducted by Institute personnel as well as to provide an objective evaluation of research results. Financial interests held by those conducting the research or the research's sponsor may compromise or appear to compromise the fulfillment of those ethical obligations and the well-being of the research subjects, as well as the integrity of the related research. Accordingly, there is a strong presumption against permitting any person with related significant financial interests to participate in the conduct of such research, particularly if the protocol involves more than minimal risk to the subject or to the public.

The primary bases for the conflict of interest rules applied to **individuals** are:

1. We have a responsibility to ensure that the education of our students is not affected by the financial or other external interests of our faculty or staff.
2. The principal loyalty of our faculty and staff in both time and energy must be devoted to MIT.
3. Research directions, goals of the projects and evaluation and sharing of results, should not be affected by the external financial interests of individual faculty or staff.
4. As a non-profit institution, MIT must ensure that faculty (and other members of the academic community) do not obtain more than incidental private financial benefit from the *significant* use of MIT resources.

While most faculty understand the inherent risk to the values of MIT implied by the first three of these issues, most faculty are unaware of the requirements flowing from MIT's status as a non-profit, charitable institution. As a 501(c)(3) tax-exempt educational organization, MIT must be organized and operated solely for exempt purposes by serving public rather than private interests. In this regard, its tax-exempt status may be put at risk if its activities are deemed to have resulted in more than incidental private benefit to a third party. MIT is required to report in its annual tax filing whether any third party has received excess private benefit from MIT.

Because of MIT's distributed leadership structure, individual faculty may be in a position to take actions on behalf of MIT which can potentially result in excess private benefit for themselves or third parties

Similarly, as an organization that relies upon financing from tax-exempt bonds, MIT must take care to ensure that its activities, and the activities of its faculty and staff, will not result in impermissible levels of private business use. Private business use exists when one or more private

parties directly or indirectly use tax-exempt bond financed space or facilities (other than as a member of the general public) in exchange for direct or indirect payments. The use by faculty of MIT facilities for the benefit of their outside business activities qualifies as private business use.

Our policies should stress full disclosure of outside activities by faculty, followed by evaluation, determination and monitoring by Department Heads and Deans. To this end, we have created a new annual disclosure form for Outside Professional Activities (OPA) which we believe resolves some of the ambiguity inherent in the previous form. It is our intention to eventually have this as an on-line form following the example set by many of our peer institutions. This is further discussed in our recommendations.

Members of the MIT Corporation also serve a public trust. Within this framework, there are policies and disclosure forms which Corporation members and senior MIT officers complete.

While rules, guideline and procedures are necessary for orderly conduct as well as clarity of purpose, the most fundamental premise, the foundation on which we behave and work with others, is trust. Trust between individuals and between the institution and those who both govern and work within it must be a core value that holds us together. Rules provide guidelines but we must believe that all will abide by them both in fact and spirit. It is this trust in others that allows us to proceed.

## **Institutional Conflict of Interest**

Recently, associations, such as the Council on Government Relations and the American Association of Universities, as well as governmental funding agencies and individual universities, have begun to focus more closely on issues of **institutional**, as contrasted with **individual**, conflict of interest. An institutional conflict of interest is defined as

A situation in which the objectivity of the research, teaching, personnel decisions, outreach or other activities of the Institute may be compromised because of an external financial or business relationship held at the institutional level that may bring inappropriate gain to the institution, any of its units or Institute officials.

We have a responsibility to ensure that the external financial and business relationships of MIT and its officials do not compromise MIT's research, teaching, outreach or other activities. An **institutional** conflict can arise by virtue of the Institute's financial interest or by virtue of its officials' financial interests or leadership roles in a particular entity or organization – essentially, an interest that might exert pressure on another person to make a particular decision or pursue a particular result. Individuals in these positions of potential influence include not only officers of the Institute, but also members of the MIT Corporation and members of its Visiting Committees, and financial interests can take the form of equity, financial support, royalties, and other compensation. The boundary between individual and institutional conflict of interest can be difficult to define. The principal issue is whether the benefit of an individual's action flows to the individual or to an institutional entity, such as the Institute itself or a school, department, or research group.

With respect to the Institute's research program, the question is whether the Institute's financial interest, or an Institute official's financial interest or leadership role in a company, influences or has the potential to influence the design, conduct, reporting, review or oversight of research or the application of MIT policies in an individual case in which the Institute stands to benefit financially. The issue is especially sensitive with respect to human subjects research. The influence may result from:

- The Institute's or an Institute official's ownership of a significant equity interest in a research sponsor;
- Significant gifts, in cash or in kind, made by the research sponsor to the Institute or the possibility of such gifts in the future;
- Significant support of other research at the Institute by the sponsor or the possibility of significant research support from the sponsor in the future; and
- The likelihood that the results of the research will affect positively or negatively the amount of royalty or other income the Institute receives from a licensee.

Institutional conflicts of interest may also arise outside of the research context. For example, it could be an actual, potential or apparent conflict of interest if:

- The Institute based, or appeared to base, its decision as to which company should be granted an exclusive license to an invention on the fact that the Institute holds an equity interest in the licensee or receives or is entitled to receive royalties or other compensation or income from the licensee under pre-existing agreements;
- An Institute official has a leadership position with a potential licensee or vendor;
- The Institute has a financial interest, or an Institute official has a financial interest or leadership role, in a company doing or proposing to do business with the Institute; or
- Decisions about the investment of the Institute's resources are made by persons involved in the day to day operations of the Institute.

MIT has a number of policies and practices intended to prevent or manage institutional conflicts of interest. By way of example,

- Any Corporation member who has, directly or indirectly through a member of his or her immediate family, any personal or business or other financial interest in any matter that comes before the Corporation or any of its committees must disclose such interest and may not participate in the discussion of the matter or vote or be present during a vote on the matter, thereby limiting the likelihood that such interest will affect the vote of other members of the Corporation.
- MIT has segregated the decision-making process with respect to its investment assets from the day-to-day operations of the Institute by establishing the MIT Investment Management Company as a division of the Institute and vesting it with the responsibility of managing MIT's real and personal property investments.
- MIT restricts the conditions under which MIT may accept research funding from a licensee of MIT intellectual property in which MIT has an equity interest.

- Decisions regarding procurement of goods and services are largely decentralized, which minimizes the risk that the Institute's or an Institute official's financial interest will affect the selection of the vendor.

## Research Policies

The Vice President for Research through the Office of Sponsored Programs (OSP) is charged with implementing MIT policies and procedures as well as Federal regulations that deal with avoiding conflict of interest in sponsored research. OSP applies MIT policies to issues involving potential conflict of interest that arise at the time of proposal submission to private industry as well as the Federal Government.

Some examples of situations that arise in the proposal review and approval process that give rise to potential conflict of interest which are either non-allowable or require a management plan to proceed are:

- Sponsored projects in which any of the involved investigators (or members of their immediate family) have employment or consulting arrangements, significant financial interests or fiduciary responsibilities with respect to the sponsor, or with subcontractors, vendors, or collaborators.
- Research projects that benefit an entity in which the faculty member/researcher or his/her family member(s) has a significant financial interest or a fiduciary responsibility.
- Sponsored projects in which any of the involved investigators have significant financial interests in the sponsor, subcontractors, or collaborators in which the nature of the project effectively provides an option for exclusive IP rights to the outside entity.

If the proposal indicates a potential conflict of interest that requires mitigation, the investigator meets with the department head / lab or center director, the Vice President for Research and the Director of OSP to develop a conflict of interest management plan. If the research proposal is to go forward, this management plan may designate an alternate P.I. for the research program and/or alternate research supervisors for the students involved. It may also require a faculty member with sufficient knowledge of the project to oversee the potential conflict in the research program and may preclude the researcher from consulting for the outside entity during the research program.

However, granting agencies within the Federal government—specifically at this time NSF and PHS (incorporating NIH, FDA, HHS, CDC)--have recently implemented a more specific framework to deal with issues of conflict of interest in research. As of this date, the NSF and PHS require that researchers submitting proposals disclose to MIT all financial interests, including those held by spouses and dependent children, (e.g. consulting income, equity, board compensation, intellectual property rights) having a value above \$10,000 or representing more than a 5% ownership interest in an entity. It is not only the principal investigator who must disclose his or her financial interests, but all investigators. Under the regulations, an investigator is any person who is responsible for the design, conduct, or reporting of research or educational activities funded or proposed for funding by NSF or PHS. These requirements affect roughly 50% of MIT faculty.

As defined by the federal government, a financial conflict of interest arises when an investigator, directly or through his or her spouse or dependent children, has a financial interest that may be impacted by his or her NSF or PHS-supported research. The government's goal is to ensure that the design, conduct, and reporting of research funded under PHS or NSF grant awards is not biased by any such financial interest.

If the research proposal goes forward, MIT must report the existence of any conflict to PHS and put in place a management plan to mitigate the conflict. NSF also requires management plans but does not need to be notified of a conflict unless the MIT deems the situation unmanageable. MIT must state that such a plan is in place but does not in general report the details of such a plan to PHS/NSF. However, upon request, the management plan must be submitted to NSF/PHF; if the plan is not satisfactory to NSF/PHS, the agencies may cease funding. Faculty who do not disclose in accordance with the federal requirements risk having their sponsored research funding suspended until such time that they do disclose.

The specific details of the federal regulations are undergoing review in response to the continuing controversies involving accusations of conflict of interest on the part of university researchers. At the time of this writing, PHS is considering changing its conflict of interest policy to prescribe standards for management plans, and to require that plans be submitted to NIH; as well as to require the establishment and use of an independent *Committee on Conflict of Interest in Research* to review disclosures and to consider implementing effective management plans should the research go forward; and to decrease the threshold for disclosure of a financial interest in an entity from \$10,000 to a \$0 threshold. We are concerned that these higher standards will be required for all research, even the large amount of survey-based research that MIT conducts with PHS funds. Further, we see this as a significant departure from the relatively standard disclosure threshold definitions that NSF and NIH have agreed to since 1995. With other federal agencies developing their own conflict policies, we may soon find ourselves needing to implement several different standards at once.

## **Human Subjects Research**

Much of the turmoil concerning conflict of interest concerns human subjects research, primarily directed at clinical trials. Concern about financial interest on the part of clinicians conducting trials who also have a substantial financial interest in the drug or product being evaluated has been intense. Several university medical schools are under investigation by the federal government as a result of such charges.

Two recent actions by medical schools underscore the pressure that this issue has created. Harvard Medical School (HMS) is instituting a policy requiring classroom disclosure to students of all possible conflicts of interest of the faculty teaching them. Because we have many joint students, through the HST program, this affects MIT faculty/instructors as well. In addition the Stanford University School of Medicine recently announced that it would be posting on its public Web site the medical- and research-related consulting activities for some 1,200 physicians and faculty affiliated with the medical school.

We believe that human subjects research will be a growing part of the research program at MIT. In addition, we see a growing complexity in the activities of MIT and its faculty in this area. Complex institutional involvements with other research entities, i.e. Broad, Whitehead, MGH, Harvard, and complex relationships with entities in other nations will likely grow. We believe that in the face of these complexities, it is important for MIT and its faculty and staff to maintain adherence to MIT policies and practices and remain under the guidance of MIT policies both in their teaching and in their research. This is particularly important in the area of human subjects research, which is bound to be a growing portion of MIT's research involvement. In addition, in our recommendations, we outline new financial disclosure requirements for MIT faculty performing human subjects research.

To aid the discussion of these issues, we have included in various Appendices: relevant MIT policies on Outside Professional Activities; MIT policies on the responsibilities of faculty members; OSP Research Policies; TLO Policies; MIT's responsibilities as a 501(c)(3) tax-exempt organization; as well as NIH's current views of university policies on conflict of interest. All of this and related material is available on the web.

## **OUTCOMES: RECOMMENDATIONS**

In an area as complex as conflict of interest in research, we make many observations, findings and recommendations to clarify policy and improve the transparency of the processes. The following sections provide fuller descriptions of the recommendations that were summarized earlier in this report. To aid the reader, our recommendations are highlighted in bold throughout the text and collected in the opening summary.

### **Faculty Disclosure of Outside Professional Activities**

While we believe that MIT's policies on conflict of interest are basically sound, we find that the various procedures used to identify potential individual conflict of interest lack completeness and clarity. This is true particularly in the area of disclosure.

Disclosure of outside professional activities, external relations with MIT students and staff, the use of MIT facilities to support outside activities, and financial holdings that may present a potential conflict of interest with respect to proposals submitted to government and industrial sponsors occurs in two ways: 1.) an annual disclosure, submitted to Department Heads, allows an appraisal of the potential conflicts of interest of a faculty member with respect to the education and research program of MIT; 2.) specific disclosures in conjunction with an external research proposal submitted through OSP at the time of proposal submission allows determination of current potential conflicts in a specific proposal and allows the construction of an effective management plan to mitigate the potential conflicts and allow the research program to go forward. Disclosure is a complex area, with several forms of information gathering and several parties having responsibility for successful determination.

For example, with changes in Federal regulations from important agencies, notably NSF and PHS, faculty submitting proposals to *these agencies* must complete a detailed on-line disclosure form (insert link) documenting in considerable detail their financial holdings related to their research as

well as that of their spouse and dependent children. Roughly 50% of MIT faculty fill out this form each year. Typically these forms are not shared with Department Heads unless OSP determines that a conflict of interest exists that would prevent a research proposal from going forward or MIT accepting the award.

In addition, emerging concern about serious conflicts of interest in research involving human subjects has led to several recommendations from prominent National committees that faculty engaged in such research not only should disclose *every* financial holding and relationship related to their research, but also in many cases, *would be prohibited* from engaging in human subjects research if any personal financial interests exists. Not all MIT faculty are subject to these two potential disclosure requirements.

However, in a process managed by the Provost, all MIT faculty fill out an annual Outside Professional Activities (OPA) form documenting their outside professional activities, time spent on both compensated and uncompensated activities, as well as reporting any outside relationships that could influence or be influenced by the results of their research. In addition, relating to MIT's current policies on the involvement of students, postdoctoral staff, or other research staff with any outside activity of their faculty supervisor, the disclosure form requests information about any students, postdocs, research staff or other MIT employees who are involved in outside activities with faculty. Under our current policies, this form is transmitted to Department Heads who forward any concerns to the Dean, and ultimately to the Provost. We later discuss the issue of sharing information on the OPA form with Laboratory Directors.

We found the past MIT faculty OPA form confusing and ambiguous. From the beginning of our work, we had determined to modify this form to promote full disclosure, relying on the interaction between the faculty and the Department Head to identify, resolve or manage any potential conflict of interest or commitment. We therefore produced a revised faculty OPA form that provides more guidance on the types of outside activities that should be reported and on the types of outside financial interests that could imply a conflict of interest. It also refers to MIT policies regarding what should be and need not be reported. We expect that faculty will be forthcoming and accurate when asked to disclose their outside interests. To this end we have added a certification to the annual disclosure form. We would consider it a serious violation if faculty were not forthcoming and accurate with the required disclosures.

A version of this new form was released and used in June, 2009 as MIT's new faculty OPA form (Attachment A). Further improvements to this form are suggested in this report and will also come from experience with the new form. The specifications and definitions of what should be reported on the OPA form are outlined in MIT Policies and Procedures, which are included as an Appendix to this report. These specifications should be updated as a consequence of our recommendations.

We gave some thought to creating a single, annual disclosure form for faculty. Federal law would require that it mirror the NSF/PHS disclosure. However, at the time the form was introduced, the decision was made by the then Provost, that the current NSF/PHS disclosures would not be shared with Department Heads out of concern for faculty privacy. Moreover, these disclosure forms are considerably more detailed than our current OPA form. Faculty expressed some concern about the privacy issues inherent in this increased level of disclosure and the sharing of this information with

Department Heads. In the end, we decided to recommend that MIT stay with the current system and use the NSF/PHS disclosures only for those faculty for whom it is mandatory.

We also discussed whether this form eventually should be completed on-line, in line with most of our peer institutions. There was however some concern expressed about the privacy issues involved with an online disclosure/OPA system. We leave that issue to future discussions.

**We recommend the use of the new faculty OPA form (that was initiated for the 2008-09 reporting cycle) and its continued update going forward**

While most faculty understand the rules surrounding the reporting of compensated and uncompensated activities, and the “one day per week” rule, there is considerable confusion surrounding outside uncompensated professional activities such as service on NIH panels, professional society responsibilities, major outside committee responsibilities, journal editorship, reviewing journal articles, etc. We have tried to clarify these distinctions as well on the revised OPA form. We believe that faculty should report the bulk of these activities only when the time involved is substantial, and that the OPA form should provide guidance as to what constitutes a substantial time commitment. We view these as valuable activities in support of MIT and view the OPA form as an opportunity for discussion. We anticipate that only in the rarest of cases would a Department Head conclude that the time spent on such worthwhile outside professional activities does in fact detract from the faculty member’s obligations to MIT.

The new (2009) form requires faculty to report any involvement of MIT staff, students, postdoctoral fellows and employees for outside professional or business interests. We also believe that: **The OPA form should also require disclosure of significant use of MIT facilities by or on-behalf-of outside entities related to the outside professional activities of the faculty and staff.** This can be a complex issue but the Department Head is the appropriate person with whom to share this information since he/she is aware of the technical details of facilities and the people and places where such use may take place and is in a position to determine when the use reported is *significant*. In some cases, consultation with the relevant Laboratory Director regarding the use of specific laboratory facilities would be appropriate. In any case, the Department Head should be made aware of such use. (*Significant use* is defined in the TLO policies. Under these policies, the use of an office, telephone, personal computer, library or machine shop is not considered *significant use*.) Extensive use of such facilities is afforded to all members of the MIT community; however individuals whose sole connection with MIT is an outside relationship with a member of the community should not be granted use of such facilities.

## **Staff Disclosure of Outside Professional Activities**

MIT has a complex array of research appointments: Senior Research Scientist, Principal Research Scientist, Postdoctoral Associate, Postdoctoral Fellow, Research Scientist, Research Affiliate, etc. In addition, there are a number of academic staff appointments, such as Lecturer and Senior Lecturer, that may not have an apparent connection with “research” activities but that nonetheless are subject to OPA reporting under MIT policy. All of these types of appointments are outlined in Policies and Procedures. For each of these appointments, MIT policies outline the privileges and responsibilities, including the presence or absence of consulting privileges. Essentially all of these appointments require the individual to submit an OPA form which would disclose outside

activities that may give rise to conflicts of interest and would document their involvement with faculty, students, postdocs or others in their outside activities. In some Schools, staff submit their OPA forms to their immediate supervisors, in other Schools, staff submit their forms to their unit heads.

MIT has traditionally used two separate forms for collecting OPA reports: one exclusively for faculty; and the other for “staff”, which by definition includes all of the non-faculty categories mentioned above, plus administrative staff. In the course of our committee discussions it became clear that there is considerable uncertainty within schools and departments regarding which categories of “staff” need to submit OPA reports (and to some extent what the consulting privileges are for some staff categories). For example: What are the reporting requirements of part-time staff? For retired faculty? For uncompensated staff? **The current staff OPA form is relatively brief, and should be improved and expanded, similar to what has been done so far with the faculty form, in order to clarify staff reporting and disclosure requirements.**

**We recommend clarification and communication of MIT policy dealing with allowable external activities for each of the staff categories, including clarification of policies governing part-time or uncompensated staff appointments.** The simple “one day per week” rule obviously does not hold for all cases, but both the current faculty form and the staff form are silent on their interpretation for part-time faculty or staff. (Note: MIT has few regular faculty who are formally “part-time”, but this issue still needs to be addressed with regard to the faculty OPA form.) Nonetheless, it is important that part-time faculty and staff, including Research Affiliates and others who may hold uncompensated appointments, report any outside relationships with MIT faculty or staff as well as any use or involvement of MIT students, postdoctoral fellows, or other staff and any significant use of MIT facilities related to their outside financial interests. We need to ensure that schools and departments have a clear understanding of the policies and are collecting both faculty and staff OPA reports in a consistent manner.

Some concern in the regard has been raised about the appointment of uncompensated Research Affiliates in situations in which they have a relationship with an outside financial interest of the faculty member who proposed their appointment. In some cases they are provided with an office and access to MIT facilities, students and staff. We suggest that: **The appointment form for Research Affiliates should include questions about outside relationships with faculty and that, at the discretion of the Department Head, Research Affiliates should be required to submit an OPA report detailing their outside relationships with faculty and their use of MIT staff, students and facilities.**

## **The Role of Department Heads**

We view the Department Head as having the key role in assessing and managing potential conflicts of interest among faculty and staff that have the potential to affect the education of our students, the relationships between faculty and staff and the integrity of research programs at MIT. Department Heads play two key roles: they receive and evaluate the annual OPA reporting form from the faculty, and in many cases, they approve research proposals going forward from faculty members in their department.

We view the annual OPA disclosure form as an occasion for a discussion between a Department Head and a faculty member about the relationship between the faculty member's outside professional activities and the faculty member's responsibility toward the Institute. In addition to the role of the Department Heads in evaluating, determining, resolving and monitoring COI through the annual OPA form, current MIT policy requires that: **Substantial new activities require prior notification and approval of the Department Head whether based on the expenditure of time anticipated or issues raised regarding personal conflict of interest and/or involvement of students, postdoctoral staff, use of MIT facilities or research staff.** The newly designed faculty OPA form attempts to collect information documenting such prior approval. **In situations in which faculty hold a dual appointment, the OPA form should be submitted to both Department Heads.**

In the event that a Department Head and an individual faculty member are not able to agree on whether a potential conflict of interest exists for a given situation, or on how to manage a recognized conflict of interest, the issue can be brought to the Committee on Outside Professional Activities for resolution.

Department Heads also have the responsibility to receive and evaluate the annual OPA form submitted by staff employed by their units.

These roles for Department Heads require discussion and training with respect to MIT policies and Federal regulations. **We recommend that MIT establish a mechanism to ensure that Department Heads have the knowledge and the tools to fulfill their responsibilities.** AOs can be very helpful in this regard. Considerable corporate memory resides with AOs and their experience in dealing with past cases should prove invaluable. In addition, on behalf of Department Heads, AOs can ensure that OPA forms are submitted to the Department Head by all personnel as required.

## **Role of Laboratory Directors**

MIT has a complex structure of organizations involved in carrying out its research program. In many cases, research proposals are submitted by faculty through their department with the approval of their Department Head. At the other end of the spectrum, many faculty carry out their research in interdepartmental research laboratories such as CSAIL and RLE, with research proposals being submitted through the Laboratory with approval of the Laboratory Director. In between, there are a variety of smaller laboratories, some interdepartmental and others within a single department. Thus the issue of whether the OPA form submitted by faculty to their Department Heads should be automatically shared with Laboratory Directors is complex. Many faculty would object to unnecessary sharing of their annual OPA forms out of privacy concerns. Others may feel that their involvement in the research in a particular laboratory is tangential or incidental to their main activities at MIT and that such involvement does not require the sharing of their OPA form.

Laboratory Directors need to be involved in the issue of faculty conflict of interest for two reasons: to provide information on potential conflicts at the time of research proposal submission; and to assess any significant use of MIT student, staff and facilities to support the outside interests of the

faculty. Even if Laboratory Directors received OPA forms, they may not contain current information related to a specific proposal.

Fundamentally, issues of potential conflict of interest, which affect only a very small percentage of the MIT faculty, can be dealt with by better communication between Department Heads and Laboratory Directors about any specific issue or concern raised by the faculty response on the OPA form. The relevant information about a specific proposal can be gathered at the time of proposal submission and shared between Department Heads and Laboratory Directors as the research proposal goes forward to OSP. We later recommend that an improved cover sheet be submitted with each proposal that would contain the necessary information to determine the existence of a potential conflict of interest. We do recommend that, if an issue of potential conflict of interest arises concerning a proposal submitted through a laboratory, then the Department Head should be involved as well in considering the formulation of any management plan to allow the research to go forward.

We urge this discretionary approach and do not recommend that all OPA forms be automatically shared with Laboratory Directors. However, this issue should be considered by the Faculty Committee on Outside Professional Activities for any additional resolution.

In many cases, the OPA forms submitted by Staff will be submitted directly to the Laboratory Directors for assessment and resolution, who will then submit any identified issue to the Vice President for Research. Also, many research appointments will be directly approved by Laboratory Directors.

### **Disclosure During Proposal Submission**

As previously mentioned, proposal submission to NSF and PHS (NIH etc.) requires completing a disclosure form mandated by Federal regulations that discloses related financial interests and relationships of investigators. When a potential conflict is identified, under MIT policies and Federal regulations, a management plan must be put in place if the research is to go forward. In more general cases, such as in the submission of a proposal to other Federal agencies or to industry, since OSP does not receive the annual OPA disclosure form from faculty, there is no mechanism to document the details of potentially-related outside involvements of faculty submitting a specific proposal. In some cases, the Department Head is aware and acts to mitigate any potential conflict or brings such potential conflicts to the attention of the Vice President for Research (and OSP). But in other cases, there is no mechanism to ensure that all potential conflicts of interest related to a specific proposal are identified and resolved at the proposal stage. This is particularly true for research proposals submitted through Centers and Laboratories rather than through departments since Department Heads typically do not see these proposals. The current proposal coversheet form used by OSP merely asks researchers to report whether or not a potential conflict exists and to check a yes/no box, reporting to OSP whether a conflict exists, without providing any substantive details to allow an independent assessment.

For cases other than submission to NSF and PHS, which already have such a form, we recommend that: **OSP should develop a more specific set of questions to construct an internal cover form for proposal submission to obtain disclosure from faculty to OSP regarding any potential**

**conflict of interest related to a specific proposal. This form would be used by the Department Head or Laboratory Director to approve the proposal going forward.** The questions on this form should mirror the questions on the OPA form focusing on potential conflicts of interest related to the specific proposal in question.

This would help to ensure that potential conflicts of interest that require mitigation are identified at the proposal stage. When this occurs, the Vice President for Research and the Director of OSP meet with the department, lab or center head and the principle investigator to discuss a management plan to mitigate any potential conflict of interest. **If the Vice President for Research determines a management plan is needed to mitigate a potential conflict of interest in the research, the Department Head, as well as the Laboratory/Center Director as appropriate, should be involved in its development, reflecting their joint responsibility for the research program, the faculty and research staff, and the education of students.** In order the plan to be approved, the researcher should develop and submit the plan, along with the Department Head, and/or Laboratory Center Director's signature on the document being submitted to the Vice President or Research

## **Protecting Students**

We place special emphasis on our responsibilities to provide our students with an open educational environment, free of external pressures arising from the outside relationships of their faculty supervisors or the demands of a past or present employer. We believe that MIT policies and practices regarding openness, publication and intellectual property supersede prior agreements that a student may have with a previous or current employer. A current or previous employer may try to place a delay on a thesis for review, or may attempt to claim IP that arises from the MIT research of a student. If these matters are covered in a research contract between the entity and MIT, this is appropriate. Otherwise, MIT should refuse the intrusion of external entities into its academic program.

Of concern are non-disclosure agreements (NDAs) that faculty may require a student to sign as a condition of his or her research participation. If MIT has made an agreement with an external sponsor that requires NDAs, this may well be appropriate. However, all such non-disclosure agreements for students and faculty that arise out of sponsored research at MIT must be approved by OSP. TLO oversees all NDAs related to material transfer agreements. In this case, MIT bears the responsibility for both examining and fulfilling the terms of the agreement and has a well developed set of policies to fulfill these responsibilities. If faculty, as part of their consulting or other outside relationship, sign NDAs, they are solely responsible for fulfilling the terms of the agreement. **Students should not be asked to sign Non-Disclosure Agreements (NDAs) in connection with their participation in faculty research projects that have not been approved by either OSP or TLO. Student signing of such NDAs must be approved by the Department Head.** NDAs have the potential to interfere with the student's ability to present and discuss their research and may violate current MIT policy on openness. The legal responsibilities imposed upon the student may be unclear or burdensome. **We recommend that MIT review the issue of NDAs in connection with the work of the Committee on MIT Technology Transfer in the 21<sup>st</sup> Century.**

NDA's are specific legal agreements. In some cases, a student might be asked to sign a more informal document acknowledging that certain information received or generated in the course of their research should remain confidential. **We recommend that all agreements signed by students acknowledging the confidential nature of information in their research be approved by Department Heads.**

Nationwide, there have been reported cases of faculty suggesting a research topic to an outside entity in which the faculty member has an interest that competes with an ongoing student research project. Care must be taken in this area since with substantial additional resources, the work may be completed more quickly by an outside entity, leaving the student without a thesis project. Faculty with outside professional activities must not formulate research programs for outside entities that have the potential to compete with or interfere with student research. Neither should they direct the research of their students to benefit such outside entities independent of its intellectual value.

Student publications generally should not be delayed for the purposes of review by an outside entity. The Dean for Graduate Education maintains policies that address special situations where delaying a student publication may be appropriate, such as in the case of patent protection. Any disputes related to a publication review by an outside entity must be resolved at the discretion of the Institute. Outside reviews must be approved by the Vice President for Research based on existing contract language. Faculty should ensure that students receive appropriate credit for intellectual property arising from their research. Faculty should also ensure that their relationship with outside entities does not unduly affect their teaching or research. In agreement with existing MIT policy, students should not be involved in the outside activities/companies of their faculty supervisors either through part time or summer employment without obtaining permission of the Department Head. Current MIT policy acts to ensure separation between the role of the faculty member as academic supervisor of a student from the student's participation in the outside professional activities of the faculty member.

## **Postdoctoral Associates and Fellows**

By MIT policy, Postdoctoral Associates and Fellows are not accorded consulting privileges. This policy is somewhat ambiguous, as they seem to be permitted to conduct independent activities outside of the work week. They are also required to submit an annual OPA form to the Department Head. Nonetheless it is important to emphasize that they should not be involved in the outside financial or consulting activities of their faculty supervisor without the specific permission of the Department Head. Not only would this raise clear issues of conflict of interest on the part of their faculty supervisor but it would significantly increase the likelihood that substantial use of MIT facilities would be made by an outside entity in violation of MIT and Federal policy. We believe that: **The policy on consulting privileges of postdocs and any involvement in the outside activities of their faculty supervisor's needs clarification with respect to the extent and character of their consulting privileges and their allowed activities.**

We are concerned about the assumption that part-time postdoctoral appointments are appropriate. In many cases, this would violate the terms of the postdoctoral appointment. However, with other sources of research funding, such a part-time appointment might be possible. We view the

postdoctoral appointment as a continuation of the education of the post-doc. Part-time postdoctoral appointments in which the postdocs spend the remainder of their time at a company in which the faculty supervisor is involved are unacceptable from many points of view. **We urge that any request for part-time postdoctoral appointments receive the highest level of scrutiny from Department Heads, Laboratory Directors as appropriate, Deans and possibly the Vice President for Research.**

### ***Committee on Conflict Of Interest in Research***

**We recommend that the Provost establish a *Committee on Conflict of Interest in Research* to provide continuing independent advice and oversight on actions taken and policies enacted to identify, avoid and/or manage conflict of interest in sponsored research.** Members of this committee will be chosen by the Provost and will consist of faculty and senior administration, as well as individuals with specific expertise and specific administrative responsibilities. It might also include individuals from outside of MIT. The committee will monitor and oversee the policies and principles used and the actions taken by the Vice President for Research, OSP and TLO to determine COI in proposal submissions, contracting, subcontracting, and licensing of intellectual property. It will review the policies used to develop management plans, put in place to mitigate potential conflicts of interest in research. This is particularly important in any contracting or subcontracting with an outside company in which a faculty member involved in the research has a consulting, ownership or Board relationship.

MIT has a variety of policies covering conflict of interest in research. OSP and TLO have policies governing the activities and procedures followed by their office. The Committee on Conflict of Interest in Research should oversee the assemblage of such policies into a common framework for the use of faculty and Department Heads. A clear framework of such policies in a central source is particularly important to provide information for faculty new to MIT as well as to provide information for students and staff.

### **Human Subjects Research**

Much of the human subject research at MIT is supported by PHS/NIH and as such falls under the disclosure rules of the Federal government. However, some human subjects research is supported by internal MIT funds or by other external organizations, resulting in no financial disclosure through OSP. However, all human subjects' research is approved by the MIT Committee on the Use of Humans as Experimental Subjects (COUHES), which does not require financial disclosure. It is also clear that human subjects research will be a growing part of the research program at MIT with a growing complexity in the activities of MIT and complex institutional involvements with other research entities, i.e. Broad, Whitehead, MGH, Harvard.

**We recommend that: All MIT faculty should remain under the guidance of MIT policies both in their teaching and in their research in the area of human subjects research,** which is bound to be a growing portion of MIT's research involvement. MIT should not cede responsibility to another entity for approval of human subjects research in a project involving MIT faculty and students with other entities in the human subjects area. If research is to be performed in another

country with different laws, we should ensure that the human subjects requirements and protocols agree with US laws and regulations.

Financial disclosure and monitoring should be expanded for faculty engaged in human subjects research. Emerging concern about serious conflicts of interest in research involving human subjects, has led to several recommendations from prominent National committees that faculty engaged in such research not only should disclose *every* financial holding and relationship related to their research, but in many cases, would be prohibited from engaging in human subjects research if any personal financial interests exists.

We recommend that: **MIT should institute a policy of full financial disclosure for faculty engaged in human subject research in cases such as research or clinical trials involving evaluation of a product or drug for human use.** This is straightforward for research supported by PHS/NSF. For research supported by MIT or another entity, a relationship between the COUHES and OSP needs to be established to incorporate financial disclosure into the approval process. The nature of the research is important in determining whether detailed financial disclosure is required in a given case. This issue can be decided by COUHES based upon the research protocol. The expertise of OSP could then play a role in gathering the required information. The Vice President for Research can determine for these cases an appropriate management plan should the proposed research go forward. (We are pleased to note that as of October 2009 COUHES requires investigators to disclose any outside financial interests that are connected with research projects undergoing COUHES review.)

### **Institutional conflicts**

Over the past couple of years, government agencies and other organizations have begun to focus on issues of institutional conflicts of interest. Most recently, the Office of Inspector General sent a questionnaire to a number of research institutions in connection with a study regarding financial interests held by institutions that received National Institutes of Health research grants. MIT has policies and practices in place that are intended to prevent or manage institutional conflicts of interest, but they cannot be found in a single location. We recommend that: **MIT should review its policies, practices and understandings relating to institutional conflicts of interest and consolidate them into a single policy framework.**

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## **Appendix**

### **Appointment of Committees on Managing Potential Conflicts of Interest in Research and MIT Technology Transfer in the 21<sup>st</sup> Century**

MIT has long-standing policies and procedures designed to preserve the integrity of its research enterprise and foster technology transfer. These policies are well developed and reflect a deep commitment to preserving the Institute's fundamental academic values and principles. However, in recent years the complexity of the research enterprise has increased, the scope and nature of intellectual property have undergone profound changes, and increasing numbers of faculty, research staff, postdocs, graduate students, and even undergraduates are involved in commercial activities. Therefore, it is both timely and appropriate for MIT to undertake a comprehensive review of its principles, policies, and procedures related to potential conflicts of interest and to technology transfer. To this end, *two ad-hoc faculty committees* were appointed by the Provost dealing with the interrelated issues in this area.

#### **Managing Potential Conflicts of Interest in Research**

This committee will review the kinds of individual and institutional relationships that could give rise to the perception or reality of conflicts of interest; assess regulations, legal requirements, and best practices at other major institutions; and examine written and practiced policies and procedures related to conflicts of interest. They will also recommend any changes to strengthen our policies and procedures; review mechanisms for monitoring and reporting conflicts of interest; examine relevant procedures within current research groups; and recommend programs for ongoing education and information exchange regarding conflict of interest in research.

Faculty appointed to this committee are:

Institute Professor Sheila E. Widnall (chair) sheila@mit.edu

Professor Steven D. Eppinger eppinger@mit.edu

Professor Gregory C. Fu gcf@mit.edu

Professor Rudolf Jaenisch jaenisch@wi.mit.edu

Professor Rae Langton langton@mit.edu

Professor Tomas Lozano-Perez tlp@mit.edu

Professor Leona D. Samson. lsamson@mit.edu

Staff:

Suzanne Glassburn slglass@mit.edu

Doug Pfeiffer dwp@mit.edu

#### **MIT Technology Transfer in the 21<sup>st</sup> Century**

A second committee was appointed to deal with issues of MIT Technology Transfer in the 21<sup>st</sup> Century.

This committee will explore ways MIT's policies, procedures, and practices can enhance and accelerate technology transfer to contribute to the economy and the welfare of the nation and the world; review industrial partnerships and the principles on which they rest; learn from best practices at peer institutions; and recommend appropriate changes to MIT's policies and procedures to enable the formation of beneficial, strategic partnerships with industry while preserving MIT's fundamental values and principles.

Faculty appointed to this committee are:

Professor Charles L. Cooney (chair)  
Professors Angela M. Belcher,  
Professor Yet-Ming Chiang  
Professor David K. Gifford  
Professor Jerry A. Hausman  
Professor Frank Thomson Leighton  
Professor Susan Lindquist  
Professor Ram Sasisekharan,  
Professor Andrew M. Scott  
Professor Duncan Simester

The two committees will coordinate fully with each other, given the strong connection between their mandates, and consult widely in the MIT community and beyond.

### **Charge to the Committee: Managing Potential Conflicts of Interest in Research**

MIT has long-standing policies and procedures designed to foster and preserve the integrity of its research enterprise and to prevent the appearance and reality of conflicts of interest. However, in recent years the complexity of the research enterprise has increased, particularly in the areas involving commercial sponsorship and technology transfer. The previously high levels of entrepreneurship and innovation at MIT have grown further and involve larger numbers of faculty, graduate students and even undergraduates. There are also new challenges associated with the increased involvement of universities in commercial activities, such as through technology transfer and investment of endowment funds.

At the same time government, the public and the media have voiced increasing concerns about these issues. There is danger that a small number of well-publicized cases could erode the traditional, high level of trust that the government and the public have accorded to research universities.

More and more federal and non-federal sponsors are requiring conflict of interest disclosures as part of the award process, and several associations have issued recent reports and recommendations regarding conflict of interest and research integrity. Concerns, which previously focused on individual conflict of interest, now also encompass institutional conflicts of interest, in which the financial interests of the institution or its senior officers are affected by the outcome of individual research programs.

Therefore, it is both timely and appropriate for MIT to undertake a comprehensive review of its principles, policies and procedures, with the goal of preserving the highest level of integrity in the conduct, products and administration of research including its role in education. The Provost, in consultation with the Chair of the Faculty, will appoint an *ad hoc* faculty Committee on Managing Potential Conflicts of Interest in Research with the following charge:

1. Explore the various kinds of individual and institutional relationships that could give rise to the perception or reality of conflicts of interest.
2. Review and assess relevant government regulations, legal requirements, and best practices at other major research institutions.
3. Review and assess MIT's written and practiced principles and values regarding conflict of interest.
4. Review and assess MIT's written policies and procedures and unwritten practices regarding conflicts of interest.
5. Coordinate with the separate ad hoc Committee on MIT Technology Transfer in the Twenty First Century, in recognition of the connection between the two studies.
6. Recommend any changes or additions to our policies, practices and procedures.
7. Review and recommend appropriate mechanisms for reporting, monitoring and managing conflicts of interest, both individual and institutional.
8. Examine current procedures within research groups that affect the education of students including restrictions on publications, authorship, credit for research advancements, lack of transparency across research groups, sharing and participation in intellectual property rights and participation in outside professional activities with faculty supervisors.
9. Review and recommend programs for ongoing education and information exchange for faculty, staff, postdocs and students regarding research integrity and conflict of interest.

## Relation between Committees

Clearly, there are significant interactions between the work of the two committees. This is illustrated by the figure below. Simplistically, the work of the Committee on Conflict of Interest in Research deals with the activities of the faculty and other senior personnel in their roles at MIT: their work with postdocs and students; their pursuit of knowledge; their relationships with outside entities and the effects of these relationships upon their effectiveness in their MIT roles. The Committee on MIT Technology Transfer in the 21<sup>st</sup> Century deals with the research inputs and outputs to/from MIT in its role in research, intellectual property agreement with outside entities and contributions to the health and economic well-being of the Nation. This entire set of questions and relationships are embedded in a framework of MIT's values and principles and its responsibilities as a not-for-profit 501(c)(3) organization, as well as the benefits and obligations MIT derives from its status as a non-profit entity and the public service it provides to the Nation.

