COI @ MIT: The People, Policy and Process Behind Financial Conflicts of Interest at MIT

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Dave McCarthy, Technology Licensing Officer
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A shared responsibility

- VPR Conflict of Interest
- Technology Licensing Office
- Office of Graduate Education
- Deans’ Offices
- Department, Lab, and Center Heads
- Collaborate 2 Innovate
- Protect Students & Educational Mission
- Make Informed Decisions
- Maintain Research Integrity
- Reduce Administrative Burden
<table>
<thead>
<tr>
<th>Key Definitions</th>
<th>Definition</th>
</tr>
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<tbody>
<tr>
<td>Conflict of Interest (COI)</td>
<td>Financial interest w/potential to compromise objectivity</td>
</tr>
<tr>
<td>Investigator</td>
<td>Independently responsible for design, conduct, and reporting of research</td>
</tr>
<tr>
<td>Significant Financial Interest (SFI)</td>
<td>Financial interest that could reasonably appear related to Institutional Responsibilities, meets $ threshold for disclosure</td>
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<tr>
<td>Institutional Responsibilities</td>
<td>Research, teaching, administration, etc.</td>
</tr>
<tr>
<td>Financial Conflict of Interest</td>
<td>SFI that could affect research design, conduct, reporting of research</td>
</tr>
<tr>
<td>Designated Official</td>
<td>Helps determine if SFI is FCOI</td>
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<tr>
<td>Institutional Official</td>
<td>MIT Vice President for Research</td>
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MIT Conflict of Interest Policy Statement

• Vice President for Research responsible for implementation and compliance with MIT Conflict of Interest (COI) Policy
• COIs (personal financial considerations) can compromise objectivity in design, conduct, and 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
• MIT must avoid or mitigate real or perceived financial COIs to preserve integrity of research and public trust
• MIT officers, faculty, and staff and others acting on its behalf avoid or mitigate real or perceived financial conflicts of interest
Brief History of Financial Conflicts of Interest in Research

- **1980**: Bayh-Dole Act permits universities to own inventions created using federal grants.
- **1990**: NIH and NSF regulations require research institutions to implement and enforce COI policies.
- **1999**: Senate investigates major financial conflicts of interest in research at Emory, Harvard, University of Texas, and Stanford.
- **2008**: New NIH regulations take effect and apply to all PHS-funded research. MIT creates COI Officer position and updates its COI policy to reflect new regulations. MIT policy is effective on August 24, 2012.
- **2011**: Jesse Gelsinger dies in a clinical trial for gene therapy at age 18. He had a mild form of a disorder, which he managed through diet and medication and was primarily healthy at enrollment. He enrolled to help find a cure for infants. An investigation by the FDA revealed that the co-PI had a financial interest in the outcome of the research and prior adverse events were not shared with patients.
- **2012**: NIH creates rigorous standards for reporting, managing, and eliminating FCOIs in amended regulations.
## 2011 NIH Regulations Increase Institutional Oversight

<table>
<thead>
<tr>
<th>1995 Regulations</th>
<th>2011 Regulations</th>
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<tbody>
<tr>
<td>Investigators determine if financial interests and research are related</td>
<td><em>Institution</em> determines if financial interests and research are related</td>
</tr>
<tr>
<td>Disclose if financial interest above $10,000</td>
<td>Disclose if financial interest above $5,000; <em>any private equity</em></td>
</tr>
<tr>
<td>Disclose outside payments for activities like consulting, equity, stocks, royalties for intellectual property rights</td>
<td>Disclose outside payments for activities like consulting, equity, stocks, royalties for intellectual property rights and travel reimbursement</td>
</tr>
<tr>
<td>No training requirement</td>
<td>Training <em>required every 4 years</em></td>
</tr>
<tr>
<td>If there are material changes in Significant Financial Interests, disclose annually.</td>
<td>If there are material changes in Significant Financial Interests, disclose <em>within 30 days of change and annually</em></td>
</tr>
<tr>
<td>No public accessibility of FCOIs</td>
<td>Public access of FCOIs <em>upon request</em></td>
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</table>
MIT’s fCOI policy is important to research(ers)

• **Promotes transparency and accountability**, reflects updated NIH, NSF and internal MIT policies and processes, **conservative $ thresholds** for reporting
• **Protects students and trainees**, on-time graduation, no undue influence over MIT research projects
• **Helps guard against bias** being introduced into research due to potential personal financial gain from outside financial interests
• **Establishes researcher responsibilities and process** for timely disclosure of SFI’s and impact on MIT research, assess real or perceived COI risk proactively
Resource links

- MIT’s fCOI policy and website
  - coi.mit.edu
  - Quick guide to COI @ MIT
- MIT ‘P&P’
  - Policies & Procedures that apply broadly to MIT faculty, staff, researchers, etc
- NIH (PHS) Revised 2011 fCOI regulations
  - Promoting Objectivity in Research under the new regulations
- NSF COI policy
  - NSF COI policy terms and definitions
- Bayh Dole Act
  - 35 USC Ch. 18: PATENT RIGHTS IN INVENTIONS MADE WITH FEDERAL ASSISTANCE
The People, Policy and Process Behind Financial Conflicts of Interest at MIT

Dave McCarthy, Officer
MIT Technology Licensing Office
Agenda

• The Role of MIT’s Technology Licensing Office
• MIT Policy and Licensing Philosophy
• Intersection of COI and TLO
Mission

MIT

• Advance knowledge and educate students in science, technology, and other areas of scholarship that will best serve the nation and the world in the 21st century

Source: https://web.mit.edu/facts/mission.html

MIT TLO

• To move innovations and discoveries from the lab to the marketplace for the benefit of the public and to amplify MIT’s global impact

https://tlo.mit.edu
The Role of MIT’s TLO (a few examples)

- **Educate** the MIT community about Tech Transfer
  - Inventor (faculty, researchers and students) relationships, IAP classes, course curriculum

- **Evaluate** new invention disclosures
  - File a patent application or not to file a patent application (much goes into this decision)

- **Make** patient, long-term investment in broad IP portfolio
  - Clear business decisions to file

- **Understand** inventors’ interests and provide broad-based support
  - Advise inventors on local resources that can help them achieve their goals

- **Make** license deals with fair terms

- **Develop** patient, supportive, long-term relationships with licensees
Tech Transfer; Lab to Market; more than one way

- Publications, presentations, seminars, conferences ...
- The graduating student or departing Post-Doc
- Collaborative/sponsored research with industry
- University seminars/courses for industry
- Outside consulting by faculty
- And... Intellectual Property licensing:
  - To research sponsor companies;
  - To startup companies;
  - To established companies interested in MIT technology.
MIT Policy and Licensing Philosophy
MIT has Clear Intellectual Property Policies

• MIT owns the patent or copyright
  • Federally funded research – Bayh-Dole Act
  • Industrially sponsored research
  • Significant use of MIT facilities

• Industrial sponsor license options
  • Non-commercial, internal research use rights at no cost, and
  • Commercial non-exclusive/royalty-free or exclusive/royalty-bearing rights

• Limits on use of MIT resources by Industry
  • Academic freedom of research, obligation to publish results, no work for hire

• Sharing of licensing revenue
  • 1/3 to inventors, 1/3 to departments, 1/3 to MIT general fund for research & education
MIT Licensing Philosophy

• Our Primary objective is the broad use of the invention in society, therefore we:

• Invest in patent protection as the foundation for successful licensing
  • Transfer the technology to capable developers
  • Technology needs time and money to get to market

• License exclusively to attract investment (and non exclusively as appropriate)
  • Especially needed for start-ups (immature tech is high risk, need potential for high reward)

• Don't let financial greed obstruct the licensing terms
  • “impact not income”
Let’s begin with Patent Licensing: What Is It?

• A license agreement is a contract between MIT and a third party in which MIT’s rights to a technology are transferred to the licensee company (without relinquishing ownership) for financial and other benefits.

• Our main goals in any license agreement are to ensure that the technology will be developed by the licensee for public benefit, complying with federal and MIT policies, and, if successful, providing a reasonable financial return to MIT and the inventors of the technology.

• License agreements are used with both startup businesses and established companies.
How licensing decisions can mitigate COI risks

- Standard features of a license will typically include negotiated financial terms, such as:
  - annual fees, milestone fees, a royalty on product sales, and reimbursement of patent costs. A license may also include equity, if a startup.
- The non-financial terms of the license are equally important:
- However because license agreements contain negotiated financial terms there exists the potential for conflict.
  - Meeting with the COI Office and TLO to identify and plan for potential conflicts can mitigate or eliminate them before they occur.
How licensing decisions can mitigate COI risks

• So... Can MIT inventors request a license to commercially develop a patent? Yes, however there are no guarantees and we don’t license to individuals.

• A TLO makes licensing decisions based on professional judgment to achieve the best possible benefit to the public,
  • without undue influence from internal or external parties.
  • Independent business decision with maximizing the public benefit in mind.

• To determine the most effective company to commercialize the technology:
  • The TLO considers several reasonable options to ensure fair and open access to potential licensees and then moves forward with the decision.
Questions? Contact Us

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(mccarthd@mit.edu)

General Email Inbox: tlo@mit.edu (Response within 2-3 days)
New Disclosure Submissions: tlo-newcase@mit.edu

Or visit https://tlo.mit.edu/ for more information

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