

**UNIVERSITY OF MASSACHUSETTS MEDICAL SCHOOL
POLICY ON CONFLICTS OF INTEREST RELATING TO
INTELLECTUAL PROPERTY AND COMMERCIAL VENTURES**

Under most circumstances, conflicts of interest involving individuals associated with the University are addressed by Chapter 268A of the Massachusetts General Laws, which governs the conduct of public officials and employees. However, pursuant to Massachusetts General Laws Ch. 75 §14A, in the area of intellectual property and technology transfer this policy is controlling. In matters not addressed by this policy, the provisions of Chapter 268A apply.

I. DEFINITIONS

As used in this Policy, the following words shall have the following meanings:

- A. Chair – The Chairperson of the Conflicts Committee, as described in detail below.
- B. Clinical Research – Research involving human subjects.
- C. Company – Any corporation, partnership, association, or other legal entity, excluding entities controlled by the United States government, the Commonwealth of Massachusetts, and the University. A Company shall include all affiliates and other associated entities.
- D. Conflict of Interest – (i) An actual or potential conflict between the personal interests of a Covered Individual and the interests of the University or the public or (ii) the reasonable appearance of such a conflict to the public.
- E. Conflicts Committee – Shall have the meaning set forth in Article III.
- F. Covered Individual – Any individual associated with the University, including without limitation faculty, staff, and students.
- G. CVIP – The University Office of Commercial Ventures and Intellectual Property.
- H. Director – The Executive Director of the CVIP.
- I. Equity – All ownership interests in a Company and all rights to obtain ownership interests in a Company, including without limitation common or preferred stock, warrants, options, and partnership units, and also including compensation arrangements based on equity performance (e.g., phantom stock). "Equity" does not include ownership interests that are held through publicly traded mutual funds.
- J. Non-Equity Compensation – All compensation other than Equity that is provided by a Company or contractually promised by a Company, including without limitation salary, gifts, royalties, consulting fees, honoraria, goods, services, and travel expenses. "Non-Equity Compensation"

does not include compensation that is provided by the University pursuant to (i) its Intellectual Property Policy or by another educational or research institution pursuant to a similar policy or (ii) University-approved research funding.

- K. Financial Interest – With respect to any Company, (i) any Equity in such Company that is directly owned by, or is under the control of, a Covered Individual or a member of his or her immediate family and (ii) Non-Equity Compensation from such Company in an aggregate amount greater than \$1,000 within the prior twelve-month period that is directly or indirectly received by or contractually promised to a Covered Individual or a member of his or her immediate family.
- L. Substantial Interest – Has either of the following meanings.
 - 1. Clinical Research – In relation to Clinical Research that is performed or directed by a Covered Individual, "Substantial Interest" has the same meaning as "Financial Interest."
 - 2. Non-Clinical Research – In relation to research other than Clinical Research that is performed or directed by a Covered Individual, "Substantial Interest" means either (i) Equity that represents more than five percent (5%) of the total equity in a Company or has a total current value of more than \$100,000 that is directly owned by, or is under the control of, such Covered Individual or a member of his or her immediate family or (ii) Non-Equity Compensation in an aggregate amount greater than the Threshold Amount within the prior twelve-month period that is received by such Covered Individual or a member of his or her immediate family.
- M. Threshold Amount – An amount of compensation that the Conflicts Committee has determined to be substantial, which amount will be established annually by the Conflicts Committee.
- N. Vice Chancellor for Research – The Vice Chancellor for Research at each campus, or where no such position exists, the Provost (or their designees).

II. ADMINISTRATION OF POLICY

A. Philosophy and Authority of Conflicts Committee

The University assumes that its faculty and staff act with the highest level of personal responsibility, integrity and commitment to the University. Nevertheless, complex situations can arise involving Conflicts of Interest that require specialized knowledge and a multi-disciplinary, problem-solving approach. Therefore, the Committee will have the authority on behalf of the University to review conflicts disclosures and to dispose of conflicts involving Financial Interests in a fair and objective manner, utilizing the knowledge and judgment of Committee members and other resources the Committee desires to access. The Committee will have broad discretion in resolving Conflicts of Interest. Over time, decisions made by the Committee may become precedents that will be used for guidance by the Committee to assure continued principled decision making. Some decisions may periodically be communicated (in a non-identified fashion) to faculty and staff in the form of advisories or guidelines. It is anticipated, for example, that promptly after its formation the Committee will establish and distribute advisories regarding typical Conflict of Interest situations with their appropriate resolution.

B. The Conflicts Committee

This Policy will be administered by a thirteen-member, University-wide Committee consisting of one member of the faculty at each campus appointed by the Chancellor; the Vice Chancellor for Research or his or her designee at each campus; the President or his or her designee; and two non-voting members appointed by the President from outside the University. The President shall annually select the Chair of the Committee from among the voting members. The faculty members of the Committee shall serve three-year terms and may not serve more than two consecutive terms.

The Committee shall meet on a regular basis. The Vice Chancellor for Research shall collect disclosures on each campus, and the Chair shall be responsible for collecting disclosure forms from the Vice Chancellors of Research, distributing forms in advance of meetings, scheduling meetings, and setting the agenda. Members may participate in meetings using voice or video-conferencing technology, provided that all members shall receive advance notice of all meetings. Decisions of the Committee will be made by a majority of the Committee's voting members in as expeditious a manner as possible and will be recorded in written minutes.

The Director or his or her designee and the General Counsel or his or her designee may attend all meetings of the Committee. The Director and the General Counsel shall be informed of the date, time and place of all meetings in the same fashion as Committee members and shall be furnished with all information provided to Committee members.

III. POLICY

A. Disclosure of Financial Interests

All Covered Individuals must disclose a Financial Interest to the Vice Chancellor for Research or his or her designee in situations in which the Financial Interest may present a Conflict of Interest involving the use of students, technology transfer activities or the outcome of research that is performed or directed by that Covered Individual with significant use of University funds, facilities or equipment. In addition, some federal agencies and non-profit organizations may require disclosure of a Financial Interest under certain circumstances. The CVIP will prepare appropriate disclosure forms and make them available on campus.

The following situations require disclosure at the time noted in each paragraph:

1. Company-Sponsored Research Proposals – If a Covered Individual intends to perform or direct Company-sponsored research at the University, and if the Covered Individual has a Financial Interest in that Company, or has received a Financial Interest from that Company, then the Financial Interest should be disclosed to the Vice Chancellor for Research and approved in accordance with this Policy before the Covered Individual submits to the University a proposal relating to such research.
2. Company-Sponsored Research – If a Covered Individual performs or directs Company-sponsored research at the University, and if the Covered Individual intends to receive or actually receives a Financial Interest in that Company or from that Company at any time (i) during the conduct of the research or (ii) within one year after cessation of the research, then the Financial Interest must be disclosed to the Vice Chancellor for Research and approved in accordance with

this Policy before it is received, if possible, or immediately after it is received, if prior disclosure is impossible.

3. Government and Non-Profit Institution Grant Applications – In general, if a Covered Individual intends to submit an application for research funding from a U.S. Government agency or a non-profit institution, then the Covered Individual must comply with any disclosure and approval procedures required by the agency or institution in connection with such application. For example, in order to comply with Public Health Service and National Science Foundation requirements, the University requires that a Covered Individual first disclose to the Vice Chancellor for Research and obtain approval of (i) certain of his or her Financial Interests that would reasonably appear to be affected by the proposed research and (ii) certain of his or her Financial Interests in any Company whose financial interests would reasonably appear to be affected by the proposed research.
4. Government and Non-Profit Institution-Funded Research – If a Covered Individual performs or directs research that is funded directly or indirectly by a U.S. Government agency or a non-profit institution, the Covered Individual must comply with any disclosure and approval procedures required by the agency or institution in connection with such funding. For example, in order to comply with Public Health Service and National Science Foundation requirements, the University requires that if a Covered Individual intends to receive or actually receives (i) a Financial Interest that would reasonably appear to be affected by the proposed research or (ii) a Financial Interest in any Company whose financial interests would reasonably appear to be affected by the proposed research, then the Financial Interest must be disclosed to the Vice Chancellor for Research and approved in accordance with this Policy before it is received, if possible, or immediately after it is received, if prior disclosure is impossible.
5. Licensing to Certain Companies – If a Company intends to obtain a license to University-owned intellectual property, directly or indirectly, and if the Covered Individual who developed, discovered, or created that intellectual property or who is involved in negotiating the license (i) becomes aware of such intention and (ii) has a Financial Interest in that Company, the Financial Interest must be immediately disclosed to the Vice Chancellor for Research, who shall notify the CVIP. If the Director or a member of the CVIP staff or the Vice Chancellor for Research has such a Financial Interest, it must be disclosed to the President or his or her designee.
6. Involvement of Students – Although involvement of students in the outside professional activities of faculty under certain circumstances may enrich the students' educational experience, such activities have the potential to create a Conflict of Interest when the faculty member has a role in supervising the student's research, classes, or graduate teaching work. Therefore, involvement of a student in the outside professional activities of a faculty member who has any role with respect to the academic progress of the student may only be undertaken after disclosure to and approval of the Department Chair. In addition, if a faculty member intends to receive or actually receives a Financial Interest in a Company, and if the Covered Individual supervises or otherwise has control over students who will be involved in work for the Company, then the Covered Individual must disclose the Financial Interest and planned student involvement to the Vice Chancellor for Research and receive approval in accordance with this Policy before the assistance of students in such work commences, even if approved by the Department Chair.

7. Changes to a Financial Interest – All Covered Individuals must disclose significant changes in previously disclosed Financial Interests. A Financial Interest that becomes a Substantial Interest is always considered a significant change.

B. Management of Conflicts

Covered Individuals are generally prohibited from having a Conflict of Interest involving a Financial Interest, unless the University has reviewed and approved both the activity and the Financial Interest that give rise to the Conflict. There are two different procedures for review and approval of these Conflicts of Interest, as set forth below. If a Conflict of Interest involves a Substantial Interest, it necessitates rigorous review that may result in prohibition or approval accompanied by conditions. On the other hand, if a Conflict of Interest involves a Financial Interest not constituting a Substantial Interest, then the Conflict of Interest ordinarily requires a less rigorous review process and ordinarily will be approved.

1. Expedited Review and Approval of Conflicts – If a Conflict of Interest does not involve a Substantial Interest, then the Conflict of Interest will ordinarily receive expedited review and approval. Under this expedited procedure, the Vice Chancellor for Research member of the Committee will review the disclosures submitted by Covered Individuals at his or her campus and either grant preliminary approval or recommend review by the full Committee. All Conflicts of Interest that are granted preliminary approval will be placed on a list that is provided to the full Committee. The Chair of the Committee may select disclosures on the list for review by the full Committee on the regular agenda; all disclosures not selected will be finally approved at the conclusion of the meeting. The Committee may establish conditions to manage certain categories of these Conflicts of Interest under special or unusual circumstances.
2. Full Review and Approval of Conflicts – If a Conflict of Interest involves a Substantial Interest, the Vice Chancellor for Research member of the Committee will forward the disclosure to the Chair for inclusion on a Committee meeting agenda. The Chair will also include on the meeting agenda any other disclosures that have been selected by the Vice Chancellor for Research as appropriate for full review. The Conflicts Committee will regularly review and dispose of all such Conflicts of Interest as described in detail below, as expeditiously as possible.
 - a. Interim Measures – The Conflicts Committee or its Chair, in consultation with the Vice Chancellor for Research of the campus, may impose any measures that it finds necessary or desirable to preserve the existing situation until a formal review is completed. Such measures may allow a Conflict of Interest to exist, with or without conditions, while a formal review is pending.
 - b. Review of Conflicts – The Conflicts Committee will formally review all conflicts disclosures that (i) involve a Substantial Interest, (ii) are recommended for full review by the Vice Chancellor for Research, or (iii) are selected by the Chair from the list of other disclosures for expedited review. In the case of a Conflict of Interest involving a Substantial Interest, the Conflicts Committee will ordinarily permit such a Conflict of Interest to exist only under certain conditions, which are intended to minimize any harm that could result from the Conflict of Interest.
 - c. Disposition of Conflicts – After completing the formal review, the Conflicts Committee may decide upon one or more of the following dispositions:

- (1) postpone consideration of the matter pending further information or investigation;
- (2) approve a Conflict of Interest because the circumstances require no action;
- (3) approve a Conflict of Interest with conditions, such as
 - public disclosure of the Financial Interest in publications describing the research results;
 - independent monitoring of the research;
 - modification of the research plan;
 - imposition of a holding period on the stock or other security in the case of a Financial Interest consisting of Equity, which will minimize the appearance of influence on the outcome of the research; or
- (4) prohibit a Conflict of Interest with compliance steps to remove the conflict, such as
 - divestiture of the Financial Interest;
 - disqualification of the Covered Individual from the research.

In addition to the above, the Committee may refer the matter to the appropriate University official or committee for disciplinary action or other appropriate action.

IV. PUBLIC STATEMENTS

A number of problems may be posed when statements are made by scientists about research before the research has been publicized in scholarly journals or symposia, when the scientist has a Financial Interest in a Company that stands to benefit from the research. In order to avoid any such occurrences at the University, all Covered Individuals who perform or direct research for a Company in which they have a Financial Interest must refrain from making public statements about the results of any research relating to that disclosure prior to (i) publication of the results in a recognized scholarly journal or (ii) presentation of the results at a recognized scholarly meeting. The Vice Chancellor for Research may make exceptions to this rule in appropriate cases. This restriction applies whether or not the University allows an activity that presents a Conflict of Interest to continue after review.

V. APPEALS

A Covered Individual may appeal an initial decision of the Committee by requesting a review of the decision by the President or his or her designee. At the President's discretion, such appeal may be a review of the documentary record of the decision or may include a meeting with the Covered Individual and member(s) of the Committee. The decision of the President shall be final.

VI. PERIODIC REVIEW OF POLICY

At least every three years following adoption of this Policy, the Conflicts Committee will conduct an evaluation of this Policy and, if necessary formulate amendments for consideration by the President of the University.