UNIVERSITY OF MASSACHUSETTS AMHERST AND BOSTON 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. <u>Chair</u> The Chairperson of the Conflicts Committee, as described in detail below.
- B. <u>Clinical Research</u> Research involving human subjects.
- C. <u>Company</u> 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. <u>Conflict of Interest</u> (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. As explained below, the University recognizes that the existence of a conflict of interest is not improper, but could lead to improper behavior. This Policy seeks to manage conflicts of interest to minimize both the appearance of improper behavior and the harm that could result from actual improper behavior. The University does not require disclosure and review of every Conflict of Interest, but only those involving a Financial Interest and certain identified activities, as described below.
- E. <u>Conflicts Committee</u> A five-campus committee that reviews and manages conflicts of interest, as further described in Article III.
- F. <u>Covered Individual</u> Any individual associated with the University, including without limitation faculty, staff, and students, but excluding members of the CVIP and Vice Chancellors for Research. Anyone who is not a Covered Individual remains subject to the more restrictive provisions of Mass. Gen. Laws Ch. 268A.
- G. <u>CVIP</u> The University Office of Commercial Ventures and Intellectual Property.

- H. <u>Director</u> The Executive Director of the CVIP.
- I. <u>Equity</u> 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. <u>Financial Interest</u> A Significant Financial Interest or Substantial Financial Interest, both as defined below.
- K. <u>Non-Equity Compensation</u> 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.
- L. <u>Significant Financial Interest</u> Has either of the following meanings.
- 1. <u>Clinical Research</u> In relation to Clinical Research that is performed or directed by a Covered Individual, "Significant Financial Interest" means (i) any Equity in a Company that is directly owned by, or is under the control of, a Covered Individual or a member of his or her immediate family or (ii) Non-Equity Compensation from a 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.
- 2. <u>Non-Clinical Research</u> In relation to research other than Clinical Research that is performed or directed by a Covered Individual, "Significant Financial Interest" means either (i) Equity that represents more than one percent (1%) of the total equity in a Company or has a total current value of more than \$10,000 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 \$10,000 within the prior twelve-month period that is received by or contractually promised to a Covered Individual or a member of his or her immediate family.
- M. <u>Substantial Financial Interest</u> Has either of the following meanings.
- 1. <u>Clinical Research</u> In relation to Clinical Research that is performed or directed by a Covered Individual, "Substantial Financial Interest" has the same meaning as "Significant Financial Interest."
- 2. <u>Non-Clinical Research</u> 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 \$100,000 within the prior twelve-month period that is received by or contractually promised to a Covered Individual or a member of his or her immediate

family.

N. <u>Vice Chancellor for Research</u> – The Vice Chancellor for Research at each campus, or where no such position exists, the Provost (or their designees).

II. PURPOSE OF POLICY

The University recognizes that interactions between University researchers and commercial entities has many beneficial effects for the University and its faculty, staff, and students, as well as companies. For example, such interactions are an especially effective means of facilitating the commercial development of University intellectual property, which benefits the public with new goods and services and stimulates economic development. The University also recognizes that its faculty, staff, and students are unlikely to undertake the significant burdens associated with such activities without additional economic incentives. These economic incentives may raise conflicts between the personal financial interests of the University researcher and the interests of the University, the Commonwealth, the academic community, and the general public. In some cases, these conflicts of interest may reasonably appear to be likely to affect the judgment of a University researcher. The University has determined that a strict prohibition of these research conflicts of interest, with disciplinary sanctions for violation, does not serve the public interest because potentially beneficial interactions with industry are lost. The University recognizes that research conflicts of interest will inevitably arise in a modern research university and that the mere existence of such conflicts, in the absence of wrongful behavior, is not improper. Therefore, this Policy seeks to manage research conflicts of interest to minimize both the appearance of an effect on the judgment of our researchers and the potential harm that could result from any conflict of interest that actually impaired their judgment. The University reserves the ability to prohibit the existence of conflicts of interest that present unmanageable risks or which would require excessive resources to manage.

III. ADMINISTRATION OF POLICY

A. Philosophy and Role 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 whose management requires specialized knowledge and a multi-disciplinary, problem-solving approach. Therefore, this Policy establishes a five-campus Conflicts Committee that will administer this Policy, review conflicts disclosures, and dispose of conflicts involving Financial Interests in a fair, objective, and confidential manner, utilizing the knowledge and judgment of Committee members and other resources the Committee desires to access. 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.

The Committee has no authority with regard to Conflicts of Interest that do not involve a Significant Financial Interest or Substantial Financial Interest. All Conflicts of Interest outside the authority of the Committee are left entirely to campus-based procedures (if any).

B. Composition of Conflicts Committee

The University will establish a thirteen-member, University-wide Committee consisting of one member of the faculty at each campus appointed under procedures established by the campus; 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 who the President may appoint 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 Director or his or her designee and the General Counsel or his or her designee may attend all meetings of the Committee.

C. Actions by Conflicts Committee

The Committee shall hold regular meetings on a monthly basis unless there are no matters for the Committee to consider or a quorum will not be achieved. The Committee shall establish procedures for special meetings. 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. 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. Decisions of the Committee will be made by a majority of the voting members in as expeditious a manner as possible and will be recorded in written minutes. These minutes shall not include any identifying information about the individuals or companies that are the subject of Committee deliberations, but shall describe situations and their resolution in general terms. The Vice Chancellor for Research shall make these written minutes available to the campus community. At the request of any Covered Individual, the Vice Chancellor for Research shall furnish that Covered Individual with complete information regarding the status of his or her disclosed Conflict of Interest.

D. <u>Recusal Procedures</u>

A Committee member shall recuse himself or herself from voting on any specific case in which that member has an actual bias or the reasonable appearance of bias. A Committee member shall recuse himself or herself from voting on or discussing, and shall exit the meeting during consideration of, any specific case in which that member has an actual conflict of interest or the reasonable appearance of conflict of interest. These recusal procedures shall not apply to votes on, or consideration of, the consent agenda as a whole. For the purposes of these Rules, the term "bias" means circumstances under which a Committee member would experience (or would reasonably appear to experience) impaired objectivity with respect to a case, and the term "conflict of interest" means circumstances in which the Committee member (or a member of his or her immediate family) has a financial interest that would be affected by (or would reasonably appear to be affected by) the disposition of a case. An example of bias is where a Committee member has a personal relationship with, or a strong opinion about an individual, either positive or negative, that could reasonably appear to impair the objectivity of the member in a case involving that individual. An example of conflict of interest is where a Committee member has a lucrative consulting relationship with a company that is the subject of a case before the Committee. Although a recusal decision will ordinarily be made by the Committee member, the Chair may require recusal of a member under two

circumstances. First, any Committee member may be challenged for bias or conflict of interest by a faculty member whose case is before the Committee. This challenge shall take the form of a confidential written explanation that the faculty member transmits to the Chair. If the Chair concurs with the challenge, the Chair may require recusal of the Committee member. Second, if the Chair has actual knowledge or a reasonable belief, based on competent information, that the Committee member has an actual bias or that a conflict of interest exists, the Chair may require recusal of the member. If the Chair requires recusal of a Committee member for any reason, or if the Chair does not require recusal of a challenged Committee member, the Chair shall include within the file a confidential written record of the basis for the decision, which shall be available for consideration on appeal.

E. Confidentiality of Disclosures

Many of the matters brought to the Committee for review and action will include information of a personal and private nature concerning the financial interests of Covered Individuals, proprietary business information, and other information of a highly confidential nature. Accordingly, the Committee will meet in closed session; all members and observers must maintain all disclosed information in strict confidence; and the Committee will take all precautions and actions necessary to preserve the confidentiality of such information. In addition, at the request of a faculty member, the Vice Chancellor for Research shall have discretion to limit disclosure of identities to University counsel and the Committee Chair, rather than the whole Committee, to satisfy the preferences of that faculty member. Information disclosed under this Policy may be further disclosed outside the University if required by applicable law, but only after the General Counsel approves such disclosure and the affected Covered Individual is notified that the information will be released.

IV. POLICY

A. Authority of Conflicts Committee

The Conflicts Committee shall have general authority to review and dispose of Conflicts of Interest involving Significant and Substantial Financial Interests together with the activities described in Section IV.B. The Committee will have broad discretion in resolving Conflicts of Interest. The Committee shall have authority to add to the list of activities in Section IV.B. as the Committee identifies additional activities that raise serious concerns. The Committee shall annually review the dollar amounts indicated in Sections I.K. and I.L. of the Policy, and shall have authority to adjust those amounts to account for inflation and other economic factors. The Committee shall have authority to interpret the Policy. The Committee shall give notice of its interpretative statements through its written minutes and periodic advisories.

B. Disclosure of Conflicts of Interest

All Covered Individuals must disclose a Significant or Substantial Financial Interest to the Vice Chancellor for Research or his or her designee in situations designated by this Policy 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. <u>Company-Sponsored Research Proposals</u> 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. <u>Company-Sponsored Research</u> If a Covered Individual performs or directs Companysponsored 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. <u>Government and Non-Profit Institution Grant Applications</u> 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. <u>Government and Non-Profit Institution-Funded Research</u> 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. <u>Licensing to Certain Companies</u> 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. <u>Involvement of Students</u> If a faculty member intends to receive or actually receives a Financial Interest in a Company, and if the faculty member supervises or otherwise has control over students who will be involved in work for the Company outside of the University, then the faculty member 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.
- 7. <u>Changes to a Financial Interest</u> All Covered Individuals must disclose material changes in previously disclosed Financial Interests. A Significant Financial Interest that becomes a Substantial Financial Interest is always considered a material change.

No disclosure is required under this Policy unless the Conflict of Interest is within one of the above categories. The Conflicts Committee has authority to add to this list. In such event, the Committee will issue an official advisory to provide notice of the change, and shall update the Conflict of Interest Disclosure Form to reflect the change.

C. <u>Management of Conflicts</u>

Covered Individuals are generally prohibited from having a Conflict of Interest that is disclosable under Section IV.B. unless the University has reviewed and allowed both the activity and the Financial Interest. There are two different procedures for review and allowance of these Conflicts of Interest, as set forth below. If a Conflict of Interest involves a Substantial Financial Interest, it necessitates rigorous review that may result in prohibition or allowance accompanied by conditions. On the other hand, if a Conflict of Interest involves a Significant Financial Interest and not a Substantial Financial Interest, then the Conflict of Interest ordinarily requires a less rigorous review process and ordinarily will be allowed.

- 1. <u>Interim Decisions</u> The University understands that transactions sometimes arise quickly and unexpectedly, such that the usual conflicts review process could cause delays that might jeopardize the transaction. Under these unusual circumstances, at the request of a Covered Individual, the Conflicts Committee or its Chair, in consultation with the Vice Chancellor for Research, may give an interim decision or otherwise impose 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. The interim decision may also prohibit the existence of the Conflict of Interest until reviewed by the Committee. As necessary, the Committee may also hold a special meeting to review a disclosure before the next regularly scheduled meeting.
- 2. <u>Expedited Review of Conflicts: Consent</u> If a disclosure involves a Significant Financial Interest but not a Substantial Financial Interest, the Conflict of Interest will ordinarily receive expedited review and allowance. Under this expedited procedure, the Vice Chancellor for Research will review the disclosures submitted by Covered Individuals at his or her campus and either grant preliminary allowance or recommend review by the full Committee. If the Vice Chancellor for Research recommends review by the full Committee, the Vice Chancellor for Research shall give written reasons for that recommendation, which shall become part of the record and shall be made available to the Covered Individual. All Conflicts of Interest that are granted preliminary allowance will be placed on a list that is provided to the full Committee.

The Chair or any Committee member may select disclosures on the list for review by the full Committee on the regular agenda; all disclosures not selected will be finally allowed in a single vote at the conclusion of the meeting. If a disclosure is selected for full review, the Chair shall give written reasons for that selection, which shall become part of the record and shall be made available to the Covered Individual. The Committee may establish conditions to manage certain categories of these Conflicts of Interest under special or unusual circumstances.

- 3. <u>Full Review of Conflicts: Regular Agenda</u> If a disclosure involves a Substantial Financial Interest, the Vice Chancellor for Research will forward the disclosure to the Chair for inclusion on a Committee meeting agenda. The Chair will also include on the meeting agenda any disclosures involving a Significant Financial Interest 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. <u>Review of Conflicts</u> The Conflicts Committee will formally review all conflicts disclosures that (i) involve a Substantial Financial Interest, (ii) involve a Significant Financial Interest and are recommended for full review by the Vice Chancellor for Research, or (iii) are selected by the Chair from the list of disclosures involving a Significant Financial Interest. In the case of a disclosure involving a Substantial Financial 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.
 - b. <u>Disposition of Conflicts</u> After completing the formal review, the Conflicts Committee may decide upon one or more of the following dispositions:
 - (1) Allow a Conflict of Interest because the circumstances require no action;
 - (2) Allow 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;
 - (3) Prohibit a Conflict of Interest with compliance steps to remove the conflict, such as:
 - divestiture of the Financial Interest in
 - disqualification of the Covered Individual from the research; or
 - (4) Postpone consideration of the matter pending further information or investigation.

4. <u>Time Periods for Decisions</u>. At the request of a Covered Individual, and under circumstances in which an urgent decision is required, the Chair shall render an interim decision (which may result in prohibition) within thirty days after receiving a complete and accurate disclosure of the Conflict of Interest. This decision will remain in effect until the Conflicts Committee renders a decision. In all other cases, the Conflicts Committee will ordinarily render a decision not later than ninety days after receiving a complete and accurate disclosure of the Conflicts Committee will use every effort to render a decision earlier than this ninety-day deadline. In appropriate circumstances, the Committee may hold a special meeting to make a decision prior to the next regularly scheduled meeting. The University strongly recommends that Covered Individuals begin the conflicts approval process at the first step of any transaction so that the review process will be completed before the transaction is completed. This will ensure that transactions will not be delayed while the conflicts review process occurs.

V. PUBLIC STATEMENTS

A number of problems my 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.

VI. APPEALS

Any Covered Individual may appeal an initial decision of the Committee by requesting a rehearing of the matter. The rehearing shall occur at the next regularly scheduled meeting of the Conflicts Committee. At the rehearing, the Covered Individual may personally appear before the Committee and shall have the right to be accompanied by counsel or a union representative. The Committee shall establish written procedures for the conduct of re-hearings. The Committee shall issue a reconsidered decision promptly after the conclusion of the rehearing.

If a Covered Individual who is a faculty member continues to disagree with the reconsidered decision of the Committee, the faculty member may request an advisory opinion from an ad hoc faculty committee composed of three members appointed by the Chancellor for that campus and three members appointed by the Faculty Senate. The faculty member and the Vice Chancellor for Research (on behalf of the Conflicts Committee) will each present their views to the ad hoc committee. The committee will adopt an opinion by vote of a majority of its members. In the event of a deadlock, the committee may adopt two opinions. The committee will transmit its written opinion to the faculty member and the Vice Chancellor for Research (who shall relay the decision to the Conflicts Committee). The Conflicts Committee shall consider the opinion of the ad hoc committee at its next regularly scheduled meeting, and may either reaffirm or change its decision.

Any Covered Individual may make a final appeal to the President. The President shall review the documentary record of the decision and, at the discretion of the President, may meet with the

Covered Individual and members of the Committee. In the case of a faculty appellant who has requested an advisory opinion from an ad hoc faculty committee, the President shall consider that opinion and shall provide a written rationale in the event of disagreement. The decision of the President shall be final.

If a Covered Individual disagrees with this final decision, the Covered Individual may exercise his or her individual legal rights to challenge the decision on the grounds that (i) due process was not followed or (ii) the decision is arbitrary and capricious, but no Covered Individual may challenge the decision on substantive grounds. Any such challenge shall be brought in a court of law located in the Commonwealth of Massachusetts. This acknowledgment by the University that a Faculty Member has the right to pursue a legal claim is not an admission by the University that any Faculty Member actually has any actionable legal claim. Rather, the University seeks to preserve the legal rights of a Faculty Member outside of the collective bargaining process after internal appeals are exhausted.

VII. ENFORCEMENT

If a Covered Individual fails to disclose a disclosable Conflict of Interest, or otherwise violates the Policy, the Committee may refer the matter to the appropriate University official or committee for disciplinary action or other appropriate action.

If a Covered Individual discloses a Conflict of Interest but refuses to accept a decision of the Committee, the Covered Individual may voluntarily eliminate the Conflict of Interest by removing the Financial Interest or ceasing the activity affected by the Financial Interest. For example, a Covered Individual could choose to retain a lucrative consulting agreement and refuse a sponsored research agreement with the same company. In this situation, no enforcement is necessary because there is no violation of the Policy.

In contrast, if a Covered Individual does not eliminate the Conflict of Interest and either proceeds with a prohibited Conflict of Interest or refuses to agree with the conditions imposed by the Committee for allowance, the Covered Individual has violated the Policy and enforcement actions are appropriate.

VIII. 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 and Trustees of the University. The Conflicts Committee will solicit comments from the Faculty Senate before formulating any amendments.