

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

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. .
- 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.

UNIVERSITY OF MASSACHUSETTS MEDICAL SCHOOL

PROCEDURE FOR THE OVERSIGHT OF INDIVIDUAL AND INSTITUTIONAL FINANCIAL INTERESTS IN HUMAN SUBJECTS RESEARCH*

(Doc. T96-039)

- I. Need for a detailed policy on oversight of Conflicts of Interest (COI).** The University of Massachusetts Medical School (UMMS) has as its stated mission “To advance the health and well-being of the people in the Commonwealth and the world through pioneering advances in education, research and healthcare delivery”. It has become increasingly apparent that in order to fulfill this mission, UMMS must engage in a variety of complex relationships with outside entities, including commercial entities such as pharmaceutical and biotechnology companies, with whom we share the critical mission of promoting the development of novel therapies for populations of individuals for whom the current health outcomes are inadequate.

In the course of these relationships, there will be occasions in which the potential for a real or apparent conflict of interest arises. Individual investigators, other faculty, administrative leaders, or the institution (UMMS) itself may be called upon to clearly delineate how and why it may be justified to act in a manner that may lead to conflicts of interest, but only insofar as those interests are fully disclosed and do not materially damage the interests of research subjects, patients, UMMS employees, UMMS itself, or the Commonwealth of Massachusetts. The purpose of this document is to provide a framework for pursuing such interactions in keeping with overall University of Massachusetts policy and accepted best practices for US medical schools.

- II. AAMC 2001 and 2002 Policies and Guidelines for the Oversight of Individual and Institutional Financial Interests in Human Subjects Research: Protecting Subjects, Preserving Trust, Promoting Progress (Parts 1 and 2).**

The Association of American Medical Colleges (AAMC) is comprised of the 137 accredited US medical schools, with participation of their associated teaching hospitals through the Council of Teaching Hospitals. As such, it represents a widely accepted source of community standards of best practice with regard to the conduct of research within academic medical centers. In 2001 and 2002, the AAMC issued two sets of Policies and Guidelines regarding the oversight of such conflicts, the first dealing with individual financial interests and the second dealing with institutional interests. Each of these reports was authored by a panel of experts and leaders in academic medicine and was thoroughly researched and referenced. These three reports (AAMC Reports) form the basis for the Guidelines and these Procedures.

The Guidelines establish the presumption that an individual who holds any Pecuniary Interests in Research with respect to Clinical Research (defined as research involving human subjects) proposed to be conducted at UMMS may not conduct that research. This presumption applies regardless of the source of funding. The same presumption is in force when the institution holds Pecuniary Interests in Research with respect to Clinical Research. A key feature of the Guidelines, however, is that this presumption is potentially rebuttable when the investigator or institution can make a compelling argument for exemption.

* These procedures are promulgated pursuant to the University of Massachusetts Conflicts Committee Guidelines for the Oversight of Individual and Institutional Financial Interests in Human Subjects Research dated December 22, 2009, as amended on May 1, 2012 (Guidelines) and were approved by the President effective as of May 1, 2012.

III. UMMS Procedures. In accordance with the standard of review established in the Guidelines (as informed by the AAMC reports) and in furtherance of the Conflicts Policy, UMMS has developed the following procedures to assist UMMS in the consideration of conflicts of interest cases involving Clinical Research.

A. Institutional COI Official: The Vice Chancellor or Vice Provost for Research (VPR) or his/her designee shall serve as the institutional COI official for UMMS, including all three schools within UMMS (the School of Medicine, the Graduate School of Nursing, and the Graduate School of Biomedical Sciences). The VPR shall be responsible for developing procedures, using available databases, to identify potential institutional financial interests in accordance with the principles established in the Guidelines and the AAMC Reports.

B. UMMS Committee for Oversight of Clinical Research involving Individual COI: This committee shall be constituted by the UMMS VPR or his/her designee, and will consist of 7 faculty members, 1 designated by the Graduate School of Nursing, 1 by the Graduate School of Basic Sciences, and 5 by the School of Medicine.

C. UMMS Committee for Oversight of Clinical Research involving Institutional COI: This committee shall also be constituted by the VPR or his/her designee, and will consist of 5 members, 3 of whom shall be external to the University of Massachusetts, and the other 2 faculty from UMMS. If either of the faculty members on the Committee has a Pecuniary Interest in the matter, they would be replaced by an ad hoc member.

D. Roles and Responsibilities:

- a. It shall be the responsibility of the investigator to inform the VPR or his/her designee when he/she perceives that any individual or institutional conflicts exist, may exist, or may be perceived to exist. This must occur prior to final Institutional Review Board (IRB) approval of the protocol in question.
- b. It shall be the responsibility of the VPR, in accordance with the Guidelines, to consider whether any additional individual or institutional conflicts of the kind described in the Guidelines exist, may exist, or may be perceived to exist with respect to Clinical Research protocols received by the IRB for approval. To accomplish this, the VPR shall use, as needed, any available databases at his/her disposal, including without limitation databases of UMMS equity and royalty interests, vendors, sponsors, donors, and financial interests of institutional officials with responsibility for design, conduct, reporting, review, or oversight of Clinical Research.
- c. These potential or suspected conflicts may also be identified by the IRB and referred to the VPR for consideration in accordance with these Procedures.
- d. If the VPR determines that the individual conflicts involve a Pecuniary Interest, the VPR or his/her designee shall inform the investigators, with a copy to the IRB, of their need to either avoid participation in such clinical research or to formally request exemption. If the VPR determines that any institutional conflicts involve a Pecuniary Interest, the VPR or his/her designee shall inform the investigators, with a copy to the IRB, of the institutional conflict and the need request exemption. This exemption request must include a description of the compelling circumstances that warrant exemption (as described in the Guidelines) and the detailed plan for monitoring of the research (also as described in the Guidelines).

- e. The VPR or his/her designee shall be responsible for forwarding such requests for exemption to the appropriate UMMS Committees described in B and C above and further to inform the IRB of this action.
- f. Once a request for exemption has been forwarded to the appropriate UMMS Committee, it shall be the responsibility of that committee to render a judgment as to whether or not compelling circumstances exist to proceed with the research as proposed.
- g. The decision for compelling circumstances shall be based upon the principles delineated in the Guidelines and the AAMC reports.
- h. Even in the presence of compelling circumstances, the applicable UMMS Committee(s) must determine whether the investigator has presented a sufficient plan to disclose the conflict to volunteer subjects and to provide external monitoring of the protocol.
- i. The judgment(s), along with a tally of the vote, shall be forwarded to the VPR or his/her designee, who shall then promptly forward the judgment(s), along with any other salient comments framing the discussion to the Provost.
- j. Formal written support or disapproval of the conclusions drawn in the judgment(s) must then be made by the Provost and by the Chancellor of UMMS.
- k. If the UMMS Committee(s) judgment(s) is to proceed with the Clinical Research and the judgment(s) is supported by the Provost and the Chancellor unanimously, or is supported solely by the Chancellor, the case shall then be referred to the Conflicts Committee by the VPR or her/his designee for review and consideration in accordance with the standard of review established in the Guidelines.
- l. The VPR or her/his designee shall present to the Conflicts Committee, in writing, the background of the case, including an explanation of the individual and institutional conflicts for consideration, the deliberations of the UMMS Committee(s), the risk-benefit analysis conducted including what compelling circumstances and special considerations were identified and considered, and the recommendation of the campus in support of the Clinical Research.
- m. The Conflicts Committee shall convene to review the case and the campus recommendation and determine the final disposition of the case. If the Conflicts Committee approves the conflict, the approval shall enumerate in writing the conditions that shall apply in order to manage and reduce the conflict in accordance with the Guidelines and the AAMC reports.
- n. Even in the presence of compelling circumstances, any approval of the Conflicts Committee will include a sufficient plan to disclose the conflict to volunteer subjects and to provide external monitoring of the protocol.
- o. If the Conflicts Committee does not approve the Clinical Research, the VPR shall inform the IRB in writing and the Clinical Research will stand as not approved. Only upon final Conflicts Committee approval may the enrollment of the first volunteer research subject commence.

**UNIVERSITY OF MASSACHUSETTS MEDICAL SCHOOL
POLICY FOR PROMOTING OBJECTIVITY
IN BIOMEDICAL RESEARCH***

WORCESTER

I. Introduction.

The National Institutes of Health and other U.S. Public Health Service (PHS) agency funding represents the largest source of funding of research activities of the University of Massachusetts Medical School. To address the increasing complexities of the financial interests held by biomedical and behavioral researchers and the resulting interactions among government, research institutions, and the private sector, the PHS has promulgated comprehensive financial conflict of interest regulations that promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded by the PHS under grants, cooperative agreements or contracts will be free from bias resulting from the financial conflicts of interest of an Investigator. The University of Massachusetts Medical School acknowledges the importance of adhering to these PHS standards in the conduct of all of its extramural funded activities. This policy is for the purpose of applying these important regulations (hereinafter, the FCOI Policy) to all of its sponsored research activities. All Investigators (as defined in III below) applying for any extramurally funded activities shall comply with the requirements of this FCOI Policy. This FCOI Policy shall be made available by the Vice Chancellor or Vice Provost for Research (VPR) on a publicly available Web site.

The United States Public Health Service (“PHS”) agencies include: National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Food and Drug Administration (FDA) and the Agency for Healthcare Research and Quality (AHRQ). The PHS regulations are entitled, “Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought and Responsible Prospective Contractors” issued at 42 CFR Part 50, Subpart F (the “FCOI Regulations”). See: <http://www.gpo.gov/fdsys/pkg/CFR-2011-title42-vol1/xml/CFR-2011-title42-vol1-part50-subpartF.xml>. For purposes of this FCOI Policy, all references to “PHS” shall be a reference to the respective PHS funding agency. The NIH Office of Extramural Research Conflict of Interest Web site contains helpful information and resources about the FCOI Regulations. See http://grants.nih.gov/grants/policy/coi/coi_faqs.htm

In addition to the FCOI Regulations and the requirements of this FCOI Policy, as embodied in this amendment, all financial interests relating to human subjects research are also subject to the requirements of the University of Massachusetts Guidelines for the Oversight of Individual and Institutional Financial Interests in Human Subjects Research (“Human Subjects Guidelines”). See <http://media.umassp.edu/massedu/policy/CoI%20Intellectual%20Policy%20Guidelines.pdf>

* This Policy is issued pursuant to the Board of Trustee’s Policy on Conflicts of Interest Relating to Intellectual Property and Commercial Ventures (DOC. T96-039) (“Conflicts Policy”), as an amendment to the Conflicts Policy to reflect changes in Federal regulation and was approved by the President effective as of August 1, 2012. This Policy shall apply to any extramural funded research activities, including but not limited to those funded by PHS agencies.

The FCOI Regulations (which are embodied in this FCOI Policy) provide for a more comprehensive level of disclosure, together with compulsory reporting to the applicable PHS agency, when applicable. Disclosure to the University of Massachusetts Medical School is required of ALL “Significant Financial Interests” that reasonably appear related to the Investigator(s) “Institutional Responsibilities.” As more precisely defined below, “Significant Financial Interests” include all travel reimbursements of any amount, any equity interest in a privately-held entity and all other financial interests having a value in excess of \$5,000. All financial interests of a lesser amount that do not require handling under this FCOI Policy (and which are not covered under the Human Subjects Guidelines) instead remain subject to disclosure and management under the Conflicts Policy. Here is a link to the Conflicts Policy:

<http://media.umassp.edu/massedu/policy/ConfInterUMW.pdf>

II. Mandatory Training

The VPR shall be responsible for ensuring that each Investigator is informed about (i) this FCOI Policy, (ii) the Investigator’s responsibilities regarding disclosure of Significant Financial Interests relating to the Investigator’s Institutional Responsibilities, and (iii) the FCOI Regulations. The VPR, through the designated institutional official(s), shall require each Investigator to complete training regarding items (i)–(iii) prior to engaging in extramurally funded activities and at least every four (4) years thereafter, and immediately when any of the following applies: (1) this FCOI Policy, the Disclosure Form or the VPR procedures are revised in any manner that affects the requirements of the Investigators; (2) an Investigator is newly appointed at the University of Massachusetts Medical School; or (3) the University of Massachusetts Medical School finds that an Investigator is not in compliance with this FCOI Policy or management plan. “Immediately” shall mean the training is provided or made accessible and the Investigators participate in the training expeditiously following the event that triggers the training requirement.

III. Disclosure Procedures

- a. The VPR shall develop and administer an efficient and effective method for soliciting and reviewing timely disclosures from Investigators planning to participate in extramurally funded activities, which may be through means of a written disclosure statement and/or electronic questionnaire (“Disclosure Form”).
- b. The Disclosure Form shall provide that the Investigator will submit the Disclosure Form no later than at the time the respective application is submitted. “Investigator” means the principal investigator stated in the application and any other personnel who would be responsible for the design, conduct, or reporting of extramural funded activities which may include, for example, consultants and unpaid collaborators. The lead principal investigator on a proposed PHS application for funding is responsible for obtaining a PHS Disclosure Form for all participating Investigators.
- c. The Disclosure Form shall ask the Investigator to list all of the Investigator’s Significant Financial Interests (and those of the Investigator’s spouse or domestic partner and dependent children) that reasonably appear to be related to the Investigator’s Institutional Responsibilities (as defined below).

“Significant Financial Interest” means (subject to the exclusions listed below):

(i) Publicly Traded-Entities - With regard to any publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, “remuneration” includes salary and any payment for services not otherwise identified as salary (*e.g.*, consulting fees, honoraria, paid authorship); “equity interest” includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

(ii) Privately Held Entities - With regard to any non-publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator’s spouse or domestic partner and dependent children) holds any equity interest (*e.g.*, stock, stock option, or other ownership interest).

(iii) Intellectual Property - Intellectual property rights and interests (*e.g.*, patents, copyrights), upon receipt of income related to such rights and interests.

(iv) Travel Reimbursements - Investigators also must disclose the occurrence of any reimbursed or sponsored travel (*i.e.*, that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their Institutional Responsibilities in the twelve months preceding the disclosure; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

The term “Significant Financial Interest” does not include: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

With respect to human subjects research, the term “Significant Financial Interest” shall include cases involving any amount of remuneration and any equity ownership. See Human Subjects Guidelines:

<http://media.umassp.edu/massedu/policy/CoI%20Intellectual%20Policy%20Guidelines.pdf>

- d. “Institutional Responsibilities” means an Investigator’s professional responsibilities on behalf of the Institution, including activities such as research, teaching, clinical or other professional practice, academic activities, scholarly events, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

The Disclosure Form must conform to the requirements of the FCOI Regulations and shall include a link to the FCOI Regulations and the NIH Conflict of Interest Web site. For items III.c(i)-(iii) above, the disclosure must include, at a minimum, the name of the entity, the nature of the financial interest (e.g., equity, consulting fee), the monetary value of the financial interest or its approximate value if the interest is one whose value cannot readily be determined, and any supporting documentation determined by the VPR or the designated official(s) as needed to make a determination of whether a FCOI exists (such as a copy of the applicable consulting agreement or stock purchase agreement). For Item III.c(iv) above, the disclosure must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and the approximate monetary value. In addition, the Investigator must cooperate with all requests from the applicable agency or sponsor for additional information as needed. All such internal disclosures shall be treated as confidential personnel information with all necessary precautions to protect any sensitive proprietary company or sponsor information.

- e. The Investigator shall update the disclosure of Significant Financial Interest during the period of the award, at least annually, in accordance with the specific time period prescribed by each VPR. One annual disclosure will suffice to cover all on-going extramural funded activities. With respect to transfers, an annual disclosure shall be made to University of Massachusetts Medical School promptly to support acceptance of the appointment or employment to the University of Massachusetts Medical School. The reporting and management plan requirements described in Article V shall then be required to be completed prior to expending any funds under a PHS funded grant, cooperative agreement or contract. In addition, an Investigator shall submit an updated Disclosure Form within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new Significant Financial Interest. The Disclosure Form shall notify the Investigator of this requirement to provide updated disclosures.
- f. All disclosures are required to be reviewed by the designated institutional official(s) in a prompt manner such that within sixty (60) days of receipt of the disclosure an assessment of the significant financial interest can be made, a management plan can be developed and all the necessary reviews and approvals can be secured, such that any required report to the applicable PHS funding agency is submitted within sixty (60) days of the determination that a FCOI (as defined in IV below) exists. The Investigator's timely cooperation with the efforts of the designated institutional official(s) is needed to ensure timely reporting. Upon a failure to make timely reporting to the PHS funding agency of a FCOI, the University of Massachusetts Medical School is required under the FCOI Regulations to conduct a retrospective review of the Investigator's activities and the research project.

IV. Management of Financial Conflicts of Interests

- a. The VPR shall designate an institutional official(s) to solicit and review Disclosure Forms from each Investigator planning to participate in, or participating in, extramural funded activities.
- b. The designated institutional official(s) must review all Disclosure Forms and determine whether an Investigator's Significant Financial Interest is related to any extramural funded project and, if so related, whether the Significant Financial Interest is a financial conflict of interest (FCOI). (The designated institutional official(s) may include a committee formed by the VPR to assist with these determinations.) An Investigator's Significant Financial Interest is related to an extramural funded project when the designated institutional official(s) reasonably determines that the Significant Financial Interest: could be affected by the extramural funded project; or is in an entity whose financial interest could be affected by that project. A financial conflict of interest (FCOI) exists

when the designated institutional official(s) reasonably determines that the Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the extramural funded project. In making the determination, the designated institutional official(s) can take into account financial interests in that same entity related to other extramural funded projects disclosed in an earlier disclosure by the Investigator.

- c. The following are examples of when an Investigator would be deemed to have a financial conflict of interest (FCOI): (i) if the Investigator (together with Investigator's spouse or domestic partner and dependent children) has a Significant Financial Interest in an entity that could be affected by the research results from a proposed extramural funded project based on an analysis of the scope and subject matter of the proposed project described in the application, or (ii) the Investigator (together with Investigator's spouse or domestic partner and dependent children) has a Significant Financial Interest in an entity that licenses technology from the University of Massachusetts Medical School which has resulted in license income and that technology is the subject of a proposed extramural funded project. In making this determination, the designated institutional official(s) may consult with all appropriate institutional and governmental officials.
- d. Following initial review by the designated institutional official(s) of whether or not the Significant Financial Interest is a FCOI, all cases involving the disclosure of Significant Financial Interest having a value greater than \$10,000 in value (measured by aggregating the various categories of interests reported) shall be submitted to the next monthly meeting of the Conflicts Committee for its consideration for expedited review or full review (depending the level of financial interest involved) in accordance with Article III.B of the Conflicts Policy. The Conflicts Committee will decide upon one of the following dispositions of the case: approval, approval with conditions or restrictions, or prohibition. All conflicts which are approved shall include a management plan which shall be implemented by an oversight committee of the University of Massachusetts Medical School. Following initial review by the designated institutional official(s) of whether or not the Significant Financial Interest is a FCOI, for all cases involving the disclosure of Significant Financial Interest having a value less than \$10,000 in value, the designated institutional official(s) shall be responsible for determining whether the potential FCOI can be managed and, if approved by the designated institutional official(s), what are the necessary components of the management plan.
- e. The management plan shall be implemented by an oversight committee of the University of Massachusetts Medical School comprised of members appointed by the VPR. Ordinarily, the oversight committee will be comprised of the VPR (or designee), the Department Chair of the Investigator(s) and the Dean of the School of the Investigator(s); provided that any proposed oversight committee member shall not have a conflicting financial interest with the company or sponsor at issue.
- f. The standards for review differ between the Conflicts Policy and this FCOI Policy (and the FCOI Regulations). The standard for review under the Conflicts Policy is whether or not an actual or potential conflict between the personal interests of a covered individual and the interests of the University of Massachusetts Medical School or the public exists, or simply the reasonable appearance of such a conflict to the public (defined as a "Conflict of Interest"). The standard for review under this FCOI Policy (and the FCOI Regulations) is whether a FCOI exists. As regard these two policies, this FCOI Policy shall govern the disclosure, management and reporting of FCOIs for the University of Massachusetts Medical School.

- g. For all management plans, examples of conditions or restrictions that might be imposed to manage conflicts of interest include, but are not limited to: (1) public disclosure of significant financial interests; (2) appointment of independent monitor(s) capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest; (3) modification of the research plan; (4) change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research; (5) reduction or elimination of the financial interest (e.g., sale of an equity interest); or (6) severance of relationships that create financial conflicts. Additional conditions and restrictions (including a lower threshold for review) shall apply to cases involving human subjects as provided for under the Human Subjects Guidelines.
- h. For all management plans, the University of Massachusetts Medical School is required to monitor Investigator compliance with the management plan on an on-going basis until the completion of the related extramurally funded project.

V. Reporting Financial Conflicts of Interests to PHS

- a. Prior to expending any funds under a PHS funded grant, cooperative agreement or contract, the University of Massachusetts Medical School, through the Office of the VPR, must report to the applicable PHS funding agency the existence of any FCOI (as defined in IV above) and assure that the University of Massachusetts Medical School has implemented a management plan in accordance with this FCOI Policy and the FCOI Regulations (as discussed in IV above). If the University of Massachusetts Medical School identifies a FCOI and eliminates it prior to the expenditure of any PHS-awarded funds, the University of Massachusetts Medical School is not required to submit a FCOI report to the respective agency. The requirements of the FCOI Regulations do not apply to Federal Phase I SBIR or STTR funding, instead those financial interests are subject to disclosure and management under the Conflicts Policy.
- b. For any FCOI reported to the respective agency relating to an on-going PHS-funded research project, an annual report that conforms to the requirements of the FCOI Regulations shall be made to the applicable funding agency by the Office of the VPR for the duration of the research project in the time and manner specified by the applicable funding agency.
- c. For any Significant Financial Interest that the University of Massachusetts Medical School identifies as being a FCOI subsequent to the Office of the VPR's initial FCOI report under the award, the report will be made to the applicable funding agency and a management plan shall be implemented, at least on an interim basis, within sixty (60) days of that identification. Such a disclosure could include a new Significant Financial Interest received by the Investigator during the on-going research project, or a Significant Financial Interest held by an Investigator who is new to the research project. However, if that FCOI is one that was not timely made to the applicable funding agency, for whatever reason, the Office of the VPR is required under the FCOI Regulations to conduct a retrospective review of the Investigator's activities and the research project. If bias is found during the course of this review, a mitigation report will also be required to be submitted. These reviews and reports must be made in accordance with the requirements of the FCOI Regulations.
- d. The elements of such a report shall include, at least, the items enumerated under the FCOI Regulations. The FCOI Regulations provide that, to the extent permitted by law, the government will maintain the confidentiality of all records of financial interests.

- e. Prior to expending any funds under a PHS-funded grant, cooperative agreement or contract, the University of Massachusetts Medical School, through the Office of the VPR, shall ensure public accessibility of information about the FCOI, via a written response to any requestor within five (5) business days of a request, of information concerning a Significant Financial Interest which was disclosed and is still held by the senior/key personnel on the project, which is determined to be related to the PHS-funded research, and which is determined to be a FCOI. The information shall consist of the information required to be provided under the FCOI Regulations. The Office of the VPR shall make
- f. With respect to activities funded by other Federal but not PHS agencies, for example the National Science Foundation, the Office of the VPR shall adhere to and comply with the reporting requirements of those agencies.

VI. Subrecipient Compliance and Reporting

- a. All proposed subrecipients under a PHS-funded research project of the University of Massachusetts Medical School shall have a financial conflicts of interest policy that conforms to the requirements of the FCOI Regulations. With respect to these subgrantees, subcontractors, and collaborators, the VPR must require these entities to enter into a written agreement and make a certification to the University of Massachusetts Medical School at the time of award that its financial conflicts of interest policy complies with the FCOI Regulations. The written agreement shall include all of the terms required under the FCOI Regulations.
- b. The University of Massachusetts Medical School, through the Office of the VPR, will report to the PHS funding agency any FCOI which is identified by any subgrantee, subcontractor, or collaborator to the University of Massachusetts Medical School in the manner required under the FCOI Regulations, prior to the expenditure of funds and within sixty (60) days of any subsequently identified FCOI.

VII. Remedies

- a. If an Investigator fails to comply with this FCOI Policy or a management plan and the non-compliance appears to have biased the design, conduct or reporting of the PHS-funded research, the University of Massachusetts Medical School, through the Office of the VPR, as required under the FCOI Regulations, shall promptly notify the agency of the corrective action taken or to be taken. In every respect, the VPR shall ensure compliance with the requirements for retrospective review and prepare a mitigation report, if needed, for submission to the applicable funding agency as required under the FCOI Regulations. The agency may take its own action as it deems appropriate, which may include suspension of funding, or require the University of Massachusetts Medical School to take further action to maintain the objectivity of the research.
- b. For clinical research projects supported by the PHS, if the Department of Health and Human Services determines that a PHS-funded project of clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, was designed, conducted, or reported by an Investigator with a FCOI that was not properly disclosed or managed as required under the FCOI Regulations, the University of Massachusetts Medical School, through the Office of the VPR, must require the Investigator(s) to disclose the FCOI in each public presentation (such as articles, manuscripts and oral presentations, including classroom materials) of the results of the research and to request an addendum to previously published presentations.

VIII. Enforcement and Sanctions

- a. All persons subject to this FCOI Policy are expected to comply with it fully and promptly. Whenever an Investigator has violated this FCOI Policy, for example, by a failure to disclose a Significant Financial Interest, the VPR or the Conflicts Committee may refer the matter to the appropriate University official or committee for disciplinary action or other appropriate action.
- b. Violations of this FCOI Policy and the FCOI Regulations that constitute falsification in proposing, performing, reporting or reviewing research shall be handled in accordance with the applicable policies and procedures governing allegations of research misconduct.
- c. In addition, with respect to conflicts of interest that are not properly disclosed and handled under this FCOI Policy, the disclosure and approval requirements of the State Ethics Law Ch. 268A apply. Violations of the State Ethics Law can lead to civil fines and criminal prosecution.

IX. Records

The University of Massachusetts Medical School, through the Office of the VPR, is required pursuant to the FCOI Regulations to maintain all Disclosure Forms and all related records of actions taken by the University of Massachusetts Medical School with respect to disclosures of financial interests for a period of three years from the date of submission of the final expenditures report to the PHS or, where applicable, from other dates specified in 45 CFR 74.53(b) and 92.42(b) for different situations. Different retention requirements may apply for other extramurally funded activities.