

**UNIVERSITY OF MASSACHUSETTS
GUIDELINES & PROCEDURES FOR THE OVERSIGHT OF INDIVIDUAL AND
INSTITUTIONAL FINANCIAL INTERESTS IN HUMAN SUBJECTS RESEARCH***

I. Introduction

The missions of the University of Massachusetts (UMass) and its five campuses include the important goal to advance the health and well-being of the people in the Commonwealth of Massachusetts, the nation, and the world through advances in education, research and knowledge. It has become increasingly apparent that in order to fulfill its mission, UMass must engage in a variety of complex relationships with commercial entities, such as, pharmaceutical and biotechnology companies, with whom we share the critical responsibility of promoting the development of novel therapies for individuals for whom current health outcomes are inadequate.

In the course of these relationships, there are occasions in which the potential for real or apparent conflicts of interest arise that might call into question the integrity of advancements that are developed by UMass. It is the responsibility of individual investigators, other faculty, administrative leaders, and the institution itself to delineate clearly how and why it may be justified to act in a manner that may involve conflicts of interest or the appearance of conflicts of interest. Justification of conflicts of interest may only be maintained insofar as those interests are fully disclosed and do not materially damage the interests of research subjects, patients, UMass employees, UMass, 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.

II. Association of American Medical Colleges (AAMC) and Association of American Universities (AAU) -- “Protecting Subjects, Preserving Trust, Promoting Progress” (Parts 1 and 2), 2001 and 2002 and “Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects Research,” 2008

The AAMC comprises the 137 accredited US medical schools with participation by their associated teaching hospitals through the Council of Teaching Hospitals. The AAU comprises 61 leading United States and Canadian universities that are distinguished by the breadth and quality of their programs of graduate education and research. As such, these organizations represent a widely accepted source of community standards of best practice with regard to the conduct of research within universities and academic medical centers. In 2001 and 2002, the AAMC and the AAU issued two sets of Policies and Guidelines regarding the oversight of conflicts of interest, the first dealing with individual financial interests and the second dealing with institutional interests. Each of these

*These Guidelines are issued pursuant to the Board of Trustees’ Policy on Conflicts of Interest Relating to Intellectual Property and Commercial Ventures (DOC. T96-039) (Conflicts Policy) and were approved by the President on December 22, 2009 and amended effective as of May 1, 2012. All terms which are capitalized but not defined within these Guidelines have the meaning ascribed to those terms in the corresponding campus Conflicts Policy.

reports was authored by a panel of experts and leaders in academic medicine and was thoroughly researched and referenced. In February 2008 the AAMC and the AAU issued a new report that refined the two earlier reports and urged United States universities and medical schools to establish clear and consistent conflicts of interest policies. These three reports (AAMC Reports) form the impetus and basis for these Guidelines.

The UMass Policy on Conflicts of Interest Relating to Intellectual Property and Commercial Ventures (Conflicts Policy) is aligned with both of the AAMC-AAU reports, and our institutional mission and vision regarding this guidance document are based upon the following principles:

- The welfare of research subjects is of foremost concern in Clinical Research studies. The Conflicts Committee affirms that all Pecuniary Interests in Research (as defined in the attachment to these Guidelines) with respect to Clinical Research are potentially problematic, and, therefore, require close scrutiny and rigorous review. Thus, UMass hereby establishes the presumption that an individual who holds any Pecuniary Interests in Research with respect to Clinical Research proposed to be conducted at UMass may not conduct that research. This presumption applies regardless of the source of funding. A key feature of these Guidelines, however, is that this presumption is potentially rebuttable when the investigator or institution can make a compelling argument for exemption. “Clinical Research” is defined in the Conflicts Policy as research involving human subjects.
- The same presumption is in force when the institution holds Pecuniary Interests in Research (as defined in the 2001 AAMC report) with respect to Clinical Research. UMass may have a conflict of interest in Clinical Research whenever the financial interests of the institution (such as an equity or royalty interest), or of an institutional official acting within his or her authority on behalf of the institution, might affect – or reasonably appear to affect – institutional processes for the design, conduct, reporting, review, or oversight of the Clinical Research. Similarly, due consideration, informed by the AAMC Reports, shall be made of any substantial gifts, major institutional purchases or non-routine supply contracts with a company that sponsors Clinical Research at UMass. Each VCR shall be responsible for developing procedures, using available databases, to identify potential institutional financial interests in accordance with the principles established in these Guidelines and the AAMC Reports.
- A Covered Individual with Pecuniary Interests in Research with respect to Clinical Research may rebut the presumption against allowing conduct of the Clinical Research and be permitted to conduct the Clinical Research only after a showing of compelling circumstances and approval by the Conflicts Committee, including its plan for managing or reducing the conflict. Similarly, compelling circumstances may exist to justify the conduct of Clinical Research within UMass despite an institutional conflict of interest.
- Whether the circumstances are deemed compelling will depend in each case upon the nature of the science, the nature of the financial interest, how closely the financial interest is related to the Clinical Research, and the degree to which the financial interest may affect or be affected by the research. Special consideration may be given to protocols that are directed at orphan diseases (as defined by the U.S. Food and Drug Administration) and to protocols for compassionate use of potential therapeutics. When the interest is very direct and the potential effects substantial, the risk is greatest, and the bar must be high. However, when the individual UMass investigator holding the financial interest is uniquely qualified by virtue of expertise

and experience, and the work could not otherwise be conducted safely or effectively without that individual, he or she would be permitted the opportunity to rebut the presumption against conducting the research by demonstrating these facts along with an effective management plan.

- Transparency of reporting of real or perceived financial conflicts of interest, whether they are individual or institutional shall be disclosed (a) within the written informed consent documents, (b) within all publications (print or electronic), and (c) within all presentations of the Clinical Research outside the University.
- A plan for effective, disinterested monitoring of the Clinical Research should be included in any request to rebut the presumption. Examples of appropriate features of monitoring include the utilization of an external data monitor (with periodic on-site inspection of source documents and reconciliation of documents with the case report forms) and the use of external data and safety monitoring committees or boards (composed of peer reviewers who periodically examine data and reports redacted by the independent study monitor). In the case of an institutional conflict of interest, it may be deemed appropriate to use an external IRB for initial protocol review.
- These Guidelines apply to all Clinical Research in which any Covered Individual participates or for which they assume any role or responsibility, whether or not the study is to be conducted at the University or at another venue such as another institution, a hospital or a private concern (and all such Covered Individuals are subject to the authority of the respective campus Institutional Review Board (IRB)).
- Often a Covered Individual who has a Pecuniary Interest in Clinical Research has made prior disclosures of related financial interests for non-Clinical Research pursuant to the Policy on Faculty Consulting and Outside Activities (DOC. T96-047), the Conflicts Policy and/or the applicable Federal financial conflict of interest regulations. However, those prior disclosures or approvals do not replace or circumvent the disclosure and approval required under these Guidelines with respect to Clinical Research.
- For Clinical Research supported by the PHS (including the NIH), 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 financial conflict of interest that was not properly disclosed or managed as required under the PHS Financial Conflict of Interest Regulations, the University, through the respective office of the VCR, must require the investigator(s) to disclose the financial conflict of interest 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.

III. Conflicts Reporting Process

- Covered Individuals shall report to the Vice Chancellor for Research (VCR) when he/she perceives that any individual or institutional conflict of interest in Clinical Research exists, may exist, or may be perceived to exist. This is in addition to reporting all financial interests to the campus Institutional Review Board (IRB).

- Upon the VCR's receipt of the disclosure of the Covered Individual, the VCR shall determine whether any individual Pecuniary Interests in Research exists, may exist, or may be perceived to exist. In addition, the VCR shall also consider whether there are institutional conflicts of interests that exist, may exist, or may be perceived to exist and whether any of those interests constitute Pecuniary Interests in Research.
- With respect to specific Clinical Research to be conducted at UMass or being conducted at UMass, it is incumbent on administrative officials with direct responsibility for the Clinical Research to immediately make known to the VCR if they hold Pecuniary Interests in Research in a commercial research sponsor or an entity that owns or controls an investigational product. The VCR shall assist these officials in making a determination whether there is a conflict of interest for consideration in the case.
- It is the responsibility of the VCR to ensure that all of these applicable individual and institutional conflicts of interests are presented for review of the Clinical Research by the campus and the Conflicts Committee.
- If any campus review procedures apply in accordance with IV. below, the VCR shall ensure that those procedures are undertaken promptly and shall notify the Conflicts Committee of his/her receipt of the disclosure and the initiation of the campus procedures.
- The VCR shall refer the Clinical Research case to the Conflicts Committee for review and consideration in accordance with the standard of review established in these Guidelines, after completion of the campus procedures, if any. The VCR 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 any campus committee(s), the risk-benefit analysis conducted including what compelling circumstances and special considerations were identified and considered, and the recommendation of the campus.
- Even in the presence of compelling circumstances, any approval will include a sufficient plan to disclose the conflict to volunteer subjects and to provide external monitoring of the protocol.
- If the Conflicts Committee does not approve the Clinical Research, the VCR shall inform the IRB in writing and the Clinical Research may not be approved.
- Only upon final approval by the Conflicts Committee may the enrollment of the first volunteer research subject commence.

IV. Campus Review Procedures

Due to the unique complexities and health and safety concerns raised by Clinical Research and the myriad of campus constituencies and administrative bodies that participate in these decisions, including the campus IRB, the campuses may, but are not obliged, to develop additional procedures, beyond those set forth herein, for assisting the VCR in the consideration of these Clinical Research cases. Such campus-specific procedures would be supplemental to those set forth herein and are not in lieu of the Conflicts Committee deliberations and determination. However, each campus may develop its procedures and submit them to the Conflicts Committee or to the President (or his/her designee) for adoption if the procedures are consistent with these Guidelines (including the principles

established in the AAMC Reports) and the Conflicts Policy and are found to not unduly delay the consideration of these cases by the Conflicts Committee.

V. Relationship of UMass Policy to Faculty Physicians employed by UMass Memorial Health Center (UMMHC)

Physicians and other providers employed by UMMHC who hold faculty or other positions (e.g., student, resident, fellow, or other health care provider) at the University of Massachusetts Medical School are Covered Individuals who are subject to the Conflicts Policy for all participation in Clinical Research within the UMMHC or elsewhere, including clinical or research sites operated by the University of Massachusetts Medical School or its divisions (including Commonwealth Medicine and the Massachusetts Biologic Laboratories). This element of the policy is in keeping with the statement in the 2002 AAMC-AAU Policy document.

Pecuniary Interest in Research (Defined)

Pecuniary Interest in Research include the following interests of the Covered Individual (and spouse/domestic partner and dependent children) that is reasonably related to the Covered Individual's Institutional Responsibilities:

With regards to **Publicly-Traded Entities**, any payment or value, including salary, consultant payments, honoraria, paid authorship, equity interest (stock, stock option or other ownership interest) during the prior twelve months.

With regards to **Privately Held Entities**, any payment or value, including salary, consultant payments, honoraria, paid authorship, equity interest (stock, stock option or other ownership interest) during the prior twelve months.

With regards to **Intellectual Property**, intellectual property rights and interests (patents, copyrights) upon receipt of income related to such rights and interests.

With regards to **Travel Reimbursements**, any reimbursed or sponsored travel related to the Covered Individual's Institutional Responsibilities during the prior twelve months (with the exception of travel that is reimbursed or sponsored by a Federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education).

The term "Pecuniary Interest in Research" **does not include**: salary, royalties, or other remuneration paid by the University to the Covered Individual if the Covered Individual is currently employed or otherwise appointed, including intellectual property rights assigned to the Institution and agreements to share royalties related to such rights; income from investment vehicles, such as mutual funds and retirement accounts; income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute 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, an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education.

"Institutional Responsibilities" means the Covered Individual's professional responsibilities on behalf of the University, 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.

**UNIVERSITY OF MASSACHUSETTS MEDICAL SCHOOL
PROCEDURE FOR THE OVERSIGHT OF INDIVIDUAL AND INSTITUTIONAL
FINANCIAL INTERESTS IN HUMAN SUBJECTS RESEARCH***

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

*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 (Doc. T96-039) dated December 22, 2009, as amended on May 1, 2012 (Guidelines) and were approved by the President effective as of May 1, 2012, as amended on December 1, 2014.

presumption is potentially rebuttable when the investigator or institution can make a compelling argument for exemption.

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, the Associate Vice Chancellor for Management, and the Chief Compliance Officer of the UMass Memorial Medical Health Center.
- 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. The investigator shall also inform the Institutional Review Board (IRB) at the time of submission 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 and/or the appropriate UMMS Committee 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. If the Conflicts Committee approves the Clinical Research, the VPR shall inform the IRB in writing and the IRB shall bring to completion its review of the protocol in question.
- p. The IRB has final authority to determine whether a conflict and its management allow the proposed research to meet criteria for approval.