Doc. T96-039 | Policy on Conflict of Interest Relating to Intellectual Property and Commercial Ventures

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 increasing 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 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

*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.

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.

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.