

UNIVERSITY OF MISSOURI
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December 16, 2009

John F. Carney, III, Chancellor
Brady J. Deaton, Chancellor
Thomas F. George, Chancellor
Leo E. Morton, Chancellor
Hal Williamson, Vice Chancellor

Re: Institutional Conflict of Interest Task Force Recommendations

Dear Chancellors and Vice Chancellor Dr. Williamson:

Pursuant to President Forsee's August 31, 2009 memorandum to you, the Institutional Conflict of Interest Task Force hereby forwards a proposed Institutional Conflict of Interest Policy for Human Subjects Research (Attachment 1 hereto). The policy is proposed in the form of an Executive Order for potential codification as Collected Rule and Regulation (CRR) 410.020, *Institutional Conflicts of Interest in Human Subjects Research*. Also enclosed is an explanatory flow chart depicting how information and decisions would progress under the policy (Attachment 2 hereto). The Task Force presented the proposed policy to President Forsee in early December and it is our understanding that the campus provosts and Vice Chancellor Williamson have been asked to solicit input from appropriate campus constituents and provide feedback by February 1, 2010.

In formulating the draft policy, the Task Force adhered to the charges set forth in the President's August 31 Memorandum. We believe that the draft policy satisfies the essential requirements of Standard I-6 and Element I.6.A. of the Association for the Accreditation of Human Research Protection Programs (AAHRPP), which require:

The Organization has and follows written policies and procedures to identify, manage, and minimize or eliminate financial conflicts of interest of the Organization that could influence the conduct of the research or the integrity of the Human Research Protection Program.

AAHRPP is the national voluntary accreditation body for human research protection programs (HRPPs). MU's HRPP achieved accreditation several years ago in order to maintain MU's synergistic relationship with the Truman Veterans Administration Medical Center, which also requires accreditation. The Truman VA was recently reaccredited, and its site visit focused heavily on institutional conflict of interest issues. MU HRPP's successful reaccreditation (the process will begin in late Spring, 2010) requires meeting AAHRPP's Standard I-6, which mandates that such a policy be in place.

During the several meetings of the Task Force, the agreed-upon approach to the President's request was to focus our initial recommendation on adoption of a focused policy that is limited in scope to address the above-cited AAHRPP requirements. In keeping with this approach, the draft policy deals with conflicts of the institution only, and we will rely on the University's existing conflict of interest (occasionally "COI" hereafter) policies for individuals to address conflicts pertaining to such areas as technology transfer and patents, as well as senior University officials. Those policies are set out in CRR 330.015, *Policy on Conflict of Interest*; 420.030, *Conflict with the Interests of Federal Grant Agencies*; 10.090, *Ethics and Conflict of Interest* (relative to the Board of Curators); and 360.020, *Summer Appointments and Consultation*. The Task Force purposely did not identify what administrator or administrative body will identify potential conflicts and make decisions on how to address them. In recommending such an initially streamlined policy, the Task Force recommends a subsequent review to further analyze, among other things, a definitive delineation of the roles and responsibilities of institutional officials and more developed procedures.

Some issues that might be reviewed during a "second phase" of UM ICOI policy development include:

- Whether the scope of the policy should be broadened beyond human subjects research to other University activities, including relationships with external entities, spin-off businesses, and other entrepreneurial activities that do not involve the HRPP.
- Whether a separate "ICOI" review committee, perhaps on each campus or perhaps at the System level, should address institutional conflicts rather than an individual administrator.
- Whether "institutional officials," "senior officers," or other upper-level University decision makers should be specifically included in an enhanced ICOI policy (as opposed to relying on the application of the current individual conflict of interest policies to them), and if so to whom/what entity disclosures should be made. Although beyond its mandate, some members of the task force also encouraged the revision and updating of the University's current individual conflicts of interest policies, specifically Sections 330.015 and 420.030 of the Collected Rules and Regulations.

- How to more fully address the procedural issues in D.4. a.-d, in particular what administrator or administrative body will identify potential conflicts and make decisions on how to address them.

The Task Force believes that the critical first step will have been achieved upon adoption of the attached draft policy, which will then need to be implemented on the campus and system levels. We appreciate the opportunity to provide the above comments and look forward to continued progress on refinement of UM policy related to ICOI issues.

Sincerely,



STEPHEN J. OWENS
General Counsel,
on behalf of the Institutional
Conflict of Interest Task Force

SJO/mb

cc: Task Force Members:

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Steve Graham
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Michele Kennett
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Mikel Lynch
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Attachment 1

Collected Rules and Regulations

Research

Chapter 410: Research Involving Humans

410.020 Institutional Conflicts of Interest in Human Subjects Research

Executive Order No. XX, X-X-09.

This policy is established to meet the institutional conflict of interest requirements of the Association for the Accreditation of Human Research Protection Programs (AAHRPP), specifically Standard I-6, under which the University must have and follow written policies and procedures to ensure that research is conducted so that financial conflicts of interest are identified, managed, and minimized or eliminated. It is intended to provide appropriate institutional safeguards to sustain a climate in which human subjects research at the University can be carried out responsibly without undue influence from its entrepreneurial and its financial aspirations. Each institutional financial interest that presents a potential for financial conflicts of interest, whether real or perceived, must be fully disclosed to the President or designee, must be managed, reduced, or eliminated, and the potential conflict of interest and management plan, if any, must be disclosed to the various IRBs so that the appropriate IRB can decide whether the interest and its management, if any, allows the human subjects research to be approved.

Conflicts of interest of University officials and employees are addressed separately in Sections 10.090 (Curators), 330.015 (all employees), and 420.030 ("investigators" on funded or proposed NSF or PHS research or educational activities).

A. **Institutional Conflict of Interest in Human Subjects Research, Defined --**

1. The University may have a conflict of interest ("institutional COI") in human subjects research whenever the interests of the institution might affect – or reasonably appear to affect – institutional processes for the design, conduct, reporting, review, or oversight of human subjects research.

B. Human Subjects Research, Defined –

1. Human subjects research for the purposes of this policy is the same as that in Section 410.010A., namely:
 - a. Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains
 - A. Data through intervention or interaction with the individual, or
 - B. Identifiable private information.
 - b. Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
2. Human subjects research requires review and approval by an appropriate, officially appointed, Institutional Review Board registered with the Office of Human Research Protections prior to project initiation, and without respect to the source of funding or sponsorship, as provided by Section 410.010B.

C. Identification of Potential Institutional Conflicts of Interest. As a general guide, the following significant financial and fiduciary interests of the University warrant formal review of potential institutional COI with respect to human subjects research, as provided in this policy:

1. Royalties: The University has the potential to receive significant milestone payments and/or royalties from the commercialization of a product based at least in part on technology that is the subject of University research.
2. Non-publicly traded equity: Through its technology licensing activities or investments related to such activities, the University has obtained an equity interest or an entitlement to equity of any value (including options or warrants) in a *non-publicly traded* company that is (i) the sponsor of human subjects research at the University, or (ii) the manufacturer or distributor of a product to be studied or tested in human subjects research at or under the auspices of the institution or based at least in part on technology developed at the University.

3. Publicly traded equity: Through technology licensing activities or investments related to such activities, the University has obtained a significant equity interest or an entitlement to significant equity (including options or warrants), in a *publicly traded* company that is (i) the sponsor of human subjects research at the institution, or (ii) the manufacturer or distributor of a product to be studied or tested in human subjects research at or under the auspices of the institution, or based at least in part on technology developed at the University.
4. Governance/Fiduciary roles: Through technology licensing activities or investments related to such activities, the University has obtained the right to appoint one or more members to the governing board of any company that is (i) the sponsor of research at the University, or (ii) the manufacturer or distributor of a product that is either studied or tested in research at or under the auspices of the University, or based at least in part on technology developed at the University.
5. Gifts from companies/sponsors. The University is offered or has received significant gifts (including, but not limited to, gifts in kind, discounts, fellowships, and unrestricted educational grants) from a person, company or a foundation established by or closely affiliated with a company that is (i) sponsoring or offering to sponsor research at the University, (ii) the manufacturer or distributor of a product that is either studied or tested in research at or under the auspices of the University, or based at least in part on technology developed at the University; or (iii) a company known to be a business competitor of companies described in (i) or (ii) above.

The following circumstances, among others, should be evaluated in the gifting context:

- a. Whether a gift is of sufficient magnitude that even when held in the general endowment, it might affect, or reasonably appear to affect, oversight of research at the University;
- b. Whether a gift is held for the express or limited benefit of a school, department, institute or other unit where some or all of the research is conducted; or

- c. Whether any institutional official who has the authority to affect or reasonably appear to affect the design, conduct, reporting, review, or oversight of the research has also been actively involved in solicitation of the gift, or in the management of the gift once received by the University.

The goal of this policy is not to preclude or discourage the University from accepting philanthropy from companies that support research, or that own or control products whose underlying technologies are developed, studied or tested in research at the University, provided that such gifts do not limit or reasonably appear to limit the professional independence of faculty and staff engaged in the research or research related activities. This policy is intended to help the University develop means of identifying and examining such circumstances, and of managing, through disclosure, separation of responsibilities, and as otherwise appropriate, any actual or reasonably apparent conflicts of interest that may result.

D. Procedures

1. As part of the IRB application process, each Principal Investigator applying for IRB approval of proposed human subjects research shall identify parties with a potential financial interest in the outcome, if known.
2. Annually by January 31 and immediately whenever there is a significant change, the Vice President for Finance and Administration and the Vice President for Research and Economic Development shall report to the President any significant financial or fiduciary interests of the University relating to human subjects research, and the campus offices of research shall report information regarding sources of research funding to the University.
3. Annually by January 31 and immediately whenever there is a significant change, each General Officer of the University shall report to the President or designee any significant gift to the University or any of its parts (including, but not limited to, gifts in kind, discounts, fellowships, and unrestricted educational grants) from a company or a foundation established by or closely affiliated with a company that is (i) sponsoring or offering to sponsor research at the University, (ii) the manufacturer or distributor of a product that is either studied or tested in research at or under the

auspices of the University, or based at least in part on technology developed at the University; or (iii) a company known to be a business competitor of companies described in (i) or (ii) above.

4. The President or his designee shall:
 - a. Identify potential institutional conflicts of interest from the information provided by the Principal Investigators, Vice Presidents of Finance and Administration and for Research and Economic Development, General Officers, campus research offices and other sources of information.
 - b. Implement an oversight process and administrative policies and procedures to address institutional conflicts of interest relating to human subjects research and to identify situations in which such conflicts may arise;
 - c. Devise and implement plans to manage, reduce, or eliminate institutional conflict of interest relating to human subjects research;
 - d. Inform the various Institutional Review Boards (IRBs) on each of the campuses of the potential institutional conflict of interest relating to human subject research and any plan to manage, reduce or eliminate it for the IRB's review of human subjects research under Section 410.020, with the IRB having the final authority to decide whether the interest and its management, if any, allows the research to be approved.

Attachment 2

HUMAN SUBJECTS RESEARCH

ICOI FLOW CHART

