February 27, 2012

TO: William A. Anderson, Chair and BOT Liaison
University Committee on Faculty Affairs

FROM: Terry A. May
Faculty Conflict of Interest Information Officer

SUBJECT: UCFA Conflict of Interest Policy Review and Feedback

I am writing to respond to the University Committee on Faculty Affairs (UCFA) concerning its review and feedback dated February 14, along with subsequent clarifications. This memorandum is based on joint discussions among and the endorsement of the Offices of General Counsel, Vice President for Research and Graduate Studies, and the Provost.

I respect the concerns expressed and respond to each in the order in which they were presented:

1. The proposed MSU-COI policy greatly exceeds the intent and scope of the PHS-COI final rule.

   We propose that the new Policy be implemented in phases by first requiring an annual report of significant financial interests (“SFI”) only from Public Health Service (“PHS”) and National Science Foundation (NSF) investigators. The PHS is revising its rules concerning “Responsibility of Applicants for Promoting Objectivity in Research,” effective August 24, 2012 but the NSF has very similar, and no less rigorous, conflict of interest requirements designed to ensure that NSF research will not be biased by any conflicting financial interest of investigators responsible for the research.

   All other investigators on sponsored projects would be required to report conflicting interests related to proposals at the time of submission as is now required. Investigators on human subjects research protocols would be required to report conflicting interests related to protocols at the time of submission as is now required by approved Association for the Accreditation of Human Research Protection Standards.

   The requirement for annual reporting under the proposed Policy would be extended beyond PHS and NSF investigators to other individuals subject to the Policy through a staggered implementation as approved by the President in consultation with the Vice President for Research and Graduate Studies (“VPRGS”). Full implementation of the Policy would be achieved by January 1, 2014. A more gradual implementation of the revised Policy would allow the necessary administrative structure to be put in place to handle the greater volume of disclosures. The schedule of implementation would be based on a number of factors, including administrative capability, any new Federal requirements, and requests for implementation by individual colleges.
2. The proposed roles and functions of the Faculty Conflict of Interest Officer (FCOIO) are many and potentially conflicting.

The FCOIO should have the responsibility and authority to implement the Policy and comply with Federal requirements. We believe that under the proposed Policy the functions of the FCOIO are well-defined and not conflicting. If there are any particular aspects of the FCOIO’s role or responsibilities that are unclear, please let me know and we will address those concerns. To alleviate the administrative burden on members of the Conflict Review Committee (“CRC”), the proposed Policy provides the FCOIO with the authority to make the initial determination of whether a reported SFI could reasonably be expected to affect, or be perceived to affect, a faculty member’s performance of a University responsibility, necessitating further review by the CRC. Formal determinations that a disclosed SFI constitutes a conflict of interest would only be made after deliberations at a convened meeting of the CRC. The CRC would also be solely responsible for recommending to the VPRGS a plan for the management of conflicting interests.

3. The proposed MSU-COI policy would require the creation of a new, large and expensive bureaucratic infrastructure to administer.

The staggered implementation described above (Concern 1) through approval of the President following consultation with the VPRGS would insure that the administrative structure is put in place to handle the expanded coverage.

4. The proposed MSU-COI policy appears to apply to all MSU faculty and staff, but not to independent consultants and contractors who work with MSU faculty and staff as required by the PHS final rule.

When carrying out PHS research through subrecipients (e.g. subcontractors), PHS regulations require the University to incorporate as part of a written agreement with the subrecipient whether the conflict of interest policy of the University or that of the subrecipient will apply to the subrecipient’s investigators. PHS regulations do not require the University to specify that its conflict of interest policy applies to subrecipients conducting PHS research.

5. The proposed MSU-COI policy includes as part of its Significant Financial Interest (SFI) statement an unclear clause of “other opportunities for tangible personal benefit”.

The current Policy includes the same language (See Section 1(b) at http://www.hr.msu.edu/documents/facacadhandbooks/facultyhandbook/facultyCOI.htm). The current Policy states, “For purposes of this Policy, a conflict of interest exists when a faculty member’s financial interests or other opportunities for tangible personal benefit may compromise, or reasonably appear to compromise, the independence of judgment with which the faculty member performs his/her responsibilities at the University.”

Frequently Asked Question #4 at https://www.msu.edu/~biomed/COI/COIHandbook.html#FAQ also addresses this issue, stating, “Situations may arise in which the execution of the faculty member’s professional responsibilities creates an opportunity for the faculty member to obtain a financial benefit in the future. For example, if a faculty member were offered,
or reasonably expected to be offered, consulting work, membership on a company’s scientific advisory board, or an investment opportunity in connection with a clinical trial conducted by the faculty member, the faculty member would have a reportable conflict of interest for that clinical trial, even if the faculty member had yet to accept any of those opportunities at the time of the clinical trial. Unremunerated service on a corporate board or on a company’s scientific advisory board may also create an "opportunity for tangible personal benefit." But, opportunities that affect a faculty member less directly may nonetheless offer tangible personal benefits to the faculty member - - a job or promotion for a family member’s child, a business contact critical to the success of the faculty member’s start-up company, a contract of importance to a valued client of the faculty member’s spouse."

6. The proposed MSU-COI policy does not specifically address the procedures and protection of MSU employees who report the violation of conflict of interest policies by others.

In response to this concern, we have revised the proposed Policy to protect the confidentiality of the review of concerns or allegations of non-compliance, stating, “The review and investigation of concerns or allegations that this Policy has been violated will be conducted confidentially to the extent permitted by law, except insofar as information needs to be disclosed so that the University may effectively investigate the matter or take corrective action.” (Section V).

7. It was unclear how parts of the proposed MSU-COI policy overlap with the current MSU Outside Work for Pay policy.

The ability for faculty to undertake Outside Work for Pay (OWP) is a privilege granted by policy. A precondition to the exercise of that privilege is compliance with all University policies, including, most particularly, the faculty conflict of interest policy.

Any significant financial interests obtained through OWP must be reported if they relate to the individual’s institutional responsibilities.

In addition, the current OWP Policy specifies (See Section IV.3. at http://www.hr.msu.edu/documents/facacadhandbooks/facultyhandbook/outsidework.htm) that, “Work for any business or other for-profit enterprise owned or operated by a faculty member or by his/her relative(s), shall be considered "pay" (whether or not the faculty member receives anything of value in consideration for the work) because of the likelihood that the faculty member's work will increase the value of the business or enterprise to the faculty member's direct or indirect financial benefit.” All current conflict of interest management plans require compliance with the OWP Policy, including this provision.

MSU does not currently have a Conflict of Commitment Policy; however, a conflict of commitment can be considered as a conflicting interest (See the definition of “other opportunities for tangible personal benefit” above under Concern 5).
8. **Allowing MSU colleges to craft their own COI policies and procedures opens the possibility for variable protection and enforcement.**
To address this concern, we have revised the proposed Policy to be clear that colleges may not adopt alternative conflict of interest policies, but may adopt addenda to the main Policy that address specific concerns or conflict of interest situations in those colleges. Permitting college-specific policy addenda would be consistent with the conflict of interest policy previously adopted by the College of Human Medicine. This approach is also consistent with the current Policy. (See Section 4(a)(ii) at: [http://www.hr.msu.edu/documents/facacadhandbooks/facultyhandbook/facultyCOI.htm](http://www.hr.msu.edu/documents/facacadhandbooks/facultyhandbook/facultyCOI.htm), which provides that, “Any college that chooses not to adopt the model procedure may develop its own procedure for its faculty to report their conflicts of interest, provided that the Vice President for Research and Graduate Studies (VPRGS) approved the procedure after consulting with the FCOIIO.”

9. **The proposed MSU-COI policy should not include the involvement of non-MSU personnel on the FCOI Board.**
In response to this concern, we have revised the proposed Policy to remove the provision that would allow the appointment of community members unaffiliated with the University as members of the CRC.

10. **The proposed MSU-COI policy does not address the required PHS final rule requirement of compliance training and an informational COI website.**
While this is a requirement and expectation of the University in connection with PHS research, the University need not include it in the Policy. This will be addressed in the “Guidelines on Conflict of Interest Pertaining to Applications for NSF and PHS Research Support,” which will be included as a supplement to the Policy.

11. **The proposed MSU-COI policy addresses confidentiality, but it appears to be in conflict with the disclosure requirements of the PHS final rules.**
The language in the proposed Policy is virtually unchanged from that in the current Policy (See Section 9 at [http://www.hr.msu.edu/documents/facacadhandbooks/facultyhandbook/facultyCOI.htm](http://www.hr.msu.edu/documents/facacadhandbooks/facultyhandbook/facultyCOI.htm). The current Policy states that, “The University shall respect the confidentiality of private financial and other private information supplied by faculty, and shall not release this information publicly unless it is legally required to do so, or unless the resolution or elimination of the conflict of interest requires the public disclosure of the information, or unless the faculty member consents to its public disclosure.”

The PHS rules require that details of all conflicts of interest must be reported to the NIH and made available to the public through a web site accessible by all or provided upon request by anyone within 5 business days. The University intends to implement the option of responding to written requests in 5 business days.
12. The proposed MSU-COI policy is unclear about the timeline for resolving claims of conflict of interest.
The proposed Policy states that decisions about conflicts of interest would be made in 30 days after receipt of the CRC’s plan and any supplemental material. This thirty-day period may be extended by the FCOIO upon the written request of the VPRGS.

13. The proposed MSU-COI policy is unclear about the conflict of interest expectations for MSU administrators and administrative staff. It is also unclear as to how possible conflict of interest claims for MSU administrators would be addressed.
The current “Standards of Official Conduct for Deans, Separately Reporting Directors, and Executive Managers” Policy (See http://www.hr.msu.edu/documents/facacadpolproc/StdOffConductDDE.htm) will continue to address conflicting interests in the execution of administrative duties. The proposed Policy would cover conflict situations where Deans, Separately Reporting Directors, and Executive Managers are acting as faculty in the completion of research, teaching, outreach, and service responsibilities.

I ask your support for revising the current Conflicts of Interest, Faculty Policy as we have agreed here in response to UCFA’s written concerns.

C: Terry Curry, Associate Provost Academic Human Resources
   J. Ian Gray, Vice President Research & Graduate Studies
   Lee Bollinger, Assistant General Counsel