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Dr. Dave Reed
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Dear Dr. Reed,

Senate Research Policy Committee (RPC) examined and discussed in detail the updates proposed by your office to the Conflict of Interest (COI) procedures of the University in response to the changing Federal Requirements which the University needs to comply with. During our discussions, existing conflict of interest procedures of the University, namely, Appendix B of the Faculty Handbook (available at <http://www.admin.mtu.edu/admin/prov/facbook/appb/bapp2.html>), new NIH frequently asked questions (available at http://grants.nih.gov/grants/policy/coi/coi_faqs.htm), the Senate Proposal 38-11 *Conflict of Interest Policy Changes*, University policy 2.6012 *Supervision of Relatives*, and finally, Board of Control policy 4.7 which establish the general guidelines in this regard have been thoroughly examined.

In summary, committee members expressed full support for the proposed changes detailed in the document titled *Procedures for the Disclosure and Management of Conflicts of Interest*, which we refer to as the *draft document*. The committee considers the involvement of faculty by establishing a committee to address issues to be a very good step and in general finds the proposed procedures detailed in Sections 4 - 12 of the mentioned document to be well developed. There are however some issues that need to be addressed. In this regard, several members of the committee expressed concern about where and how this document fits with other related documents, as it sometimes includes inconsistent use of terms and occasionally includes text which can be interpreted as *policies* while describing procedures. We discuss these issues in detail together with our specific recommendations.

1 General Issues

General issues expressed by committee members center around how the draft document, once finalized, will be integrated into existing procedures of the University and how it relates to established policies. In this regard:

1. It is not clear to the committee how the proposed changes as written would be integrated into the existing COI procedures of the University, primarily the Faculty Handbook. As the draft specifically concentrates on sponsored research, it is not a comprehensive, stand-alone COI document that can serve the needs of the University in all areas. In the current COI procedures there are five categories of conflict, one of which includes sponsored research (Category 4.4). Since the draft document and Appendix B are different in organization and content, it is clear that a future effort is needed to integrate the two.
2. The draft document introduces new definitions and modifies several definitions. The draft redefines and categorizes *Conflict of Interest*. The document also modifies the prior definitions, most notably, the term *Significant Financial Interest*. The committee believes that in order to have a unified document, these terms should be visited carefully and it should be made clear what each term means. Having two definitions of the same term in two different documents is likely to create confusion in practice. This issue can be addressed by marking new terms clearly. In those cases where the definition of a term is extended or redefined, a reference to the old use of the term can be made. For example, it is possible to modify section 3.2. title with either a footnote, or state explicitly that the definition of Significant Financial Interest has changed based on new Federal Regulations.

In summary, the committee feels that the document should avoid introducing new definitions as much as possible and refer to existing definitions in the Conflict of Interest Document of the University (e.g., BOC 4.7). Examples of such definitions include *Conflict of Commitment* and *Conflict of Interest*, both of which are well defined in current policies and procedures and it is not clear if this document modifies or extends them.

2 New Procedures

1. Several members of the committee expressed concerns in relation to the procedure outlined in Section 4.4, particularly about the timing of the determination of a potential conflict as it relates to a sponsored project. There is general consensus that the implied timing by the procedure appears to be too late for most sponsored projects. Currently, the Sponsored Programs Office (SPO) does not obtain an authorized signature on an award or, in cases of unilateral awards (ones where no University signature is required, such as NSF), does not request a sponsored index to be established by Sponsored Programs Accounting (SPA) until a potential conflict has been mitigated by the Conflict of Interest Coordinator (COIC). Once SPO receives word from the COIC that all has been mitigated, SPO proceeds with the processing of the award. The draft states that the potential conflict must be finalized prior

to funds being expended which happens after an index is established. This is too late in the award process.

2. Again, in relation to the timing of the determination (i.e., Section 4.4), the outlined process should in no way slow the transmittal and proposal submission process. We believe reporting and determination by the COIC should be independent of the SPO consideration of proposals. Expressed simply, there is no conflict of interest until a given proposal is funded and those funds are subsequently misused. Some proposals have deadlines for when contractual documents need to be initiated or submitted so this must be considered in the procedures. COI ratification could be accomplished up to two months after a proposal is submitted.
3. It would seem that the second paragraph in Section 8.3 would mandate specific actions (e.g., requesting addendums) under any COI. The committee feels that there must be some threshold before these actions are enforced. For example, it would be reasonable to consider these actions if the COIC determines there was bias resulting from the Conflict of Interest.
4. In general, the determination of a Conflict of Interest requires certain preconditions. In this regard, some committee members indicated that Primary Investigators (PI) and Co-primary Investigators (Co-PI) working on scientific projects do not have supervisory roles with respect to each other. In fact, there are many projects where two or more PIs have equal roles, although in practice one of the Co-PIs assumes the management of finances and he/she is declared to be the PI for the project. As a result, it is not clear how and if the University Policy 2.6012 should apply to PIs and Co-PIs. It is also understood that sponsored projects involve work which can be contracted out. Such cases would clearly require scrutiny in relation to the Supervision of relatives criteria. In other words, established procedures should not discourage collaboration, yet, in doing so, they should not allow conflicts to go on unmitigated. The committee feels these issues should be carefully weighted.
5. Draft document Section 8.4 outlines sanctions and state that sanctions may include termination (Senate Proposal 38-11). The committee feels that the section should contain a clear description of an appeal process by referencing appropriate University documents to avoid confusion and provide a clear path for the procedures to be followed should this action is employed.
6. Finally, the draft appears to be incomplete in relation to subcontractors. The revised Health and Human Services (HHS) regulations include procedures that must be followed when HHS funds are passed through universities to potential subcontractors. In this regard, it appears that according to the revised HHS regulations, Michigan Tech would be responsible for asking about and receiving COI information from any potential subcontractor. The committee feels that the draft must spell out these issues as well.

Clarification of the following points in the document will be most helpful:

1. In several places, the document refers to University's Conflict of Interest Policy (e.g., Section 8.1). It will be better if these references are more precise (i.e, BOC 4.7).
2. Terms such as *all investigators* (Section 10.2) are confusing. Instead, PIs and Co-PIs can be used, unless others are not meant to be included (such as senior personnel).

3 Specific Recommendations

The committee makes two recommendations, namely a short-term recommendation, and a longer term recommendation:

1. Given the deadline that the University needs to comply with the Federal regulations, the committee recommends the current draft document to be adopted after being updated to focus specifically on new procedures (e.g., Section 4 and beyond) and in doing so addressing only what the committee understands to be its purpose, which is to outline the federal procedural changes, and how they are addressed such as “including a change which moves the burden of deciding whether or not a conflict exists from the individuals to the university itself”. This task can be accomplished by revising Section 3 of the document and referencing to existing policy and procedure documents in which the conflicts of interest definitions are clearly laid out. In cases where new terms and definitions are necessary, these terms can be described and their rationale can be expressed in that section.
2. As a longer term recommendation, the committee finds that the University’s Conflict of Interest Policies and Procedures are out-dated, difficult to understand, and difficult to locate, mostly because the related information is scattered into several documents. As employees of the University are responsible for knowing the COI policies and procedures, these procedures must be well laid out and must be easily accessible. The committee recommends that once the draft procedures are adopted and hence the compliance requirements of Federally mandated regulations are satisfied, a new effort must be initiated to merge this document and all other applicable COI documents into a coherent, single document which clearly spells out the procedures to be followed by both Staff and the Faculty in dealing with the issues of Conflicts of Interest. We understand that while this is not an easy task, it is necessary to avoid confusion and better compliance with the policies established by the Board of Control.

Sincerely,



Soner Onder, Chair
Senate Research Policy Committee