

Subject: Response to Comments

From: Dave Reed <dreed@mtu.edu>

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To: Soner Onder <soner@mtu.edu>, Rudy Luck <rluck@mtu.edu>, Joanne Polzien <jpolzien@mtu.edu>, pcharles@mtu.edu, "cmb >> Cathy Banfield" <cmbanfie@mtu.edu>

Soner:

My responses to the SRPC comments on the draft COI procedures are given below. After you look over, if you want to meet and discuss, let me know.

First, thanks again to the SRPC for the time and effort spent reviewing the draft procedures. I know what is involved, and appreciate everyone's contributions.

By your numbering:

1.1 - The intent will be to replace current policy with the Senate's proposal from last year. We haven't done that yet because the new regs state that new procedures have to be in place within 30 days of adoption of the new policy, so we've been waiting to get the procedures moved along before finalizing the new policy. We are analyzing whether Board action is required and if it is, our intent is for the Board to adopt the new policy at the August meeting.

Also on 1.1, the draft procedures will replace the COI procedures in the Faculty Handbook - the five categories will be gone, replaced by the significant financial interests, etc. I know its confusing and sorry this wasn't more clear for the SRPC.

1.2 - The federal definitions of conflict of interest and significant financial interest have changed. When drafting the new procedures, we thought about a 'changes' section and left it off to avoid confusion. There is a similar section on the NIH site, but after talking to folks here and elsewhere, we decided to keep the procedures clear with only the current definition. If SRPC thinks we need a 'Summary of Changes' link on the website we will work on that this summer - let me know.

Section 2

2.1 and 2.2 - Agree completely with SRPC that we do not want to add another step prior to submission. WRT 2.1, we could say at the end of section 4.4 of the draft, "... must be finalized to the satisfaction of the COIC before an index will be established for the project" instead of the current wording about expending funds. Again, if you confirm with me that you think we should do that, I will make the change.

In 2.2, the new regs make clear that in the feds view a conflict can exist at the time a proposal is submitted, not only after a proposal is funded.

2.3 - Understand the SRPC comments about a threshold before requesting addenda; the wording in the draft section 8.3, though, is straight from NIH who as I understand them clearly feel that there should be zero tolerance for failing to disclose or manage. In practice, I think these recommendations will be from the retrospective review and appropriate consideration to seriousness and intent can be incorporated by the COIC.

2.4 - agree completely, and note that once we put these coi procedures in place, we will learn from experience and as new situations arise, and we will almost assuredly find areas we need to revise to make practicable.

2.5 - understand the comment. How would it sound in section 8.4 to change the wording and reword the second line to be "Sanctions, which may include termination, are to be graduated, in accord with relevant University policy and procedures, and reflect the seriousness of the violation" That would send any sanctions down the current path that for tenured faculty would involve CATPR, etc. as appropriate. Let me know.

2.6 The subcontract monitoring is a big discussion point nationally here and I think it may evolve as these new regs are implemented. The point is a good one and true, and for now instead of putting in the procedures I think we will handle through terms and conditions of the subcontracts - that seems to be the approach being taken by peer institutions, at least many of them.

at the end of section 2:

1. We can do this in the final copy next August once the policy and these procedures are final.
2. Actually the investigators term is defined in federal regs and include in the definitions (section 3.4) - includes more than PIs or co-PIs; includes anyone - could be grad student, could be consultant, could be PI and co-PI, could be technician or senior personnel, etc.

Section 3

Both these points really get down to rollout, or phase-in, however you want to look at it. Agree that this summer the immediate goal is to meet the regulatory requirements, which means implement for anyone with NIH funding or who is proposing to NIH. We were thinking of rolling out to all funded investigators over the next year, and then to the rest of campus the year after that. Reasoning is that NSF is going to come out in the next year, and if we start small with the NIH people, we can increase in size as we learn how these procedures work, what needs to be changed, etc. [one thing I have actually learned is that with procedures as complex as these, we will not get it right the first time now matter how much time and effort and thought we put into it - if we have something that meets the regs, then as we gain experience we can make revisions over the next couple of years to fine tune, simplify, clarify, etc.]. I certainly agree with the committees second comment about unifying documents and making them easily available, both within the campus community and to the public as the new regs require us to do

There were a few questions above I would appreciate if you get back to me on - if you think it would be helpful to meet in person, Cathy can find a time if you let her know. Likewise, if you think it would be valuable for me to meet with the whole committee, I more than willing to do so if you just let her know.

Dave R

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