APPROVED - UO Senate ad hoc COI-C Committee Meeting Minutes
Friday, January 16, 2009, Johnson Hall Conference Room
3:00 p.m. to 4:35 p.m.

Voting Members Present: Peter Gilkey, Chair, Jim Brau, John Bonine, Rob Horner, Richard W. Linton, Russ Tomlin, and Kyu Ho Youm

Non-voting Members Present: Lynette Schenkel, and Meg Rowles

CALL TO ORDER

1. INTRODUCTIONS
Peter Gilkey, Chair, called the meeting to order and introductions were made.

[As stated in a December 12, 2008 memorandum from Richard W. Linton, Russ Tomlin, and Paul van Donkelaar, the UO Senate ad hoc COI-C Committee is charged with reviewing and, where needed, suggesting revisions to the draft COI-C policy to meet essential legal and policy requirements with a keen sensitivity to academic freedom and the culture of a public research university. The committee is to make a focused effort to consider the policy and associated disclosure form. It is anticipated that the revised draft will be presented at the March 11, 2009 UO Senate meeting.]

2. UPDATE BY THE CHAIR
The Chair noted that he posts items more or less continuously to the UO Senate COI-C web site (http://www.uoregon.edu/~uosenate/dirsen089/COICOCC.html) and committee members should check that site frequently and look at documents as appropriate. Items will be posted linearly and will now include a date. His emails to committee members will include a specific subject line.

Both Gilkey and Linton noted they had spoken with Greg Bolt, reporter for The Register-Guard, about COI-C issues. Gilkey extended an invitation to Bolt to attend the Town Hall meeting on Wednesday, January 21, 2009. Bolt may contact other members of the committee. Gilkey reminded the committee members that they should not represent themselves as representing the university. Committee member opinions should clearly represent individuals opinions, not necessarily university policy. Although not required, it is a professional courtesy to notify the administration if committee members talk with the press.

Gilkey has sent emails to all of the individuals who had posted a blog on the ORCR COI-C web site (with a few exceptions). He invited these individuals to the Town Hall meeting and encouraged them to provide him with additional feedback. He is also receiving input from the campus community in response to the announcement about this committee.

Gilkey was asked by Brau and Youm to forward all email he received regarding COI and COC to all committee members in an unedited format. They felt it was important for the committee to hear directly all of the concerns of the UO community.

At the request of Paul van Donkelaar, UO Senate President, Gilkey directed all comments regarding the composition of the committee to Paul at paulvd@uoregon.edu .

Questions were raised as to how the agenda for this meeting was selected and how agendas in the future would be set. Gilkey and Linton noted that the agenda for this meeting, with the exception of agenda item #4, was agreed upon at the end of the January 7, 2009 organizational meeting and that the focus of this meeting would be on background materials to familiarize committee members with past efforts. Gilkey noted that agenda item #4, the possible splitting of COI and COC issues, had come up since the last meeting and, after a discussion with the Senior Vice Provost, Gilkey felt this should be added to today's agenda.

[See agenda item # 6 Other Matters for consensus agreement on the setting of future agendas.]

3. BRIEFING ON WHITE BINDER OF COMMITTEE MATERIALS

A majority of committee members stated they had already reviewed the binder materials provided by the Office for Responsible Conduct of Research. The samples policies in the notebook predominately come from the schools that are commonly used to compare to our own institution (8 peer comparators). There was a broad search of AAU institutions across the county for what factors would be important in matters of COI and COC.

Schenkel explained the history of COI-C at the UO and the challenges working toward a comprehensive policy and disclosure. She noted that the current COI policy, established in 1995 and revised in 2001, was widely distributed to deans and department heads. There is no documentation to show management or implementation follow through after that. The records indicate that the COI disclosures done at that time were predominately done through the Office of the Vice President for research and were completed by faculty in the hard sciences who were engaged with spin-off companies and licensed technologies. There was also a form for Request for Prior Approval of Outside Activities, (addressing conflict of commitment procedures) which has also been little used.

In 2005, and still on-going, issues developed with regard to the federal Reading First program and included testimony before the US Congress by two of our faculty. It is known that these issues are still not complete and still not settled. The strong opinion is that there will be further action on that investigation which may or may not come down to an individual level.

In 2006, an internal audit by the Oregon University System (OUS) of the UO Office of Technology Transfer recommended expanding and strengthening the potential conflict of interest disclosure reporting requirements for faculty. Other system schools experienced similar findings in their audits by OUS during this time.

Schenkel provided examples (from 1998 and onwards) of major research and academic institutions and private entities that had serious conflict of interest cases - some of which expanded into conflicts of commitment as well as possible misconduct in research – some institutions were even shut down.

Stanford received some substantial fines and underwent some special audit provisions, as did Johns Hopkins, Penn State, and Minnesota. At the University of Vermont, Dr. Eric Poehlman, former tenured research professor at the UV College of Medicine, was the first individual whose conflicts of commitment led to misconduct of research, personal indictment and a prison sentence for his actions.

Samuel Waksal, was employed at Stanford, the NCI of the NIH, Tufts, and Mt. Sinai, all of which sent him on without reviewing his conflict of interest issues, resulting in a major scandal.

Dr. Jan Hendrik Schön, formerly of Bell Labs, is an example of COI issues in the commercial community. Harvard ended up with an $11 million dollar fine. More recently, Rush University was fined $3.9 million and there was a $1 million dollar fine at the University of Alabama at Birmingham.

Of these incidents, the most dramatic was the University of Minnesota which received a $32 million dollar fine. At issue was the sale of a drug without the proper licensing, which had been developed with federal funds. There are five key points that are relevant for the academic community to know: (1) in the area of grants management, the UM's expanded authorities (including their ability to roll-over grant funds from year to year) were removed; (2) they were given 55 corrective actions as an institution. (3) By 2004, six years after the incident, the UM estimated that they spent an additional $48 million dollars to implement the required corrections.

(4) Their Chair of Surgery, a key involved person, was asked to resign and was personally indicted on 18 felony counts. Although he was later exonerated, his academic career was ended. The University brought in a group to review the incident/environment that created this conflict and that group decided that tenure did not contribute to compliance with conflict of interest, sparking the "tenure wars" of 1996-1998. (5) The UM also experienced a 20% drop in federal funding for both research and academic endeavors over the next several years. UM is now considered the "gold standard" in most matters compliance related.

The issues across the country, plus UO's own issues, led to a UO COI-C working group brought together by Linda Brady. As that group met, it was clear that COI had elements of COC and that both would need to be addressed in the policy review process. The four academic deans who were participating in that group had concerns about infrastructure support and the ability to implement the procedures in either the existing policy or in any revisions that might be made. It was determined that the Office for Responsible Conduct of Research (ORCR) should work closely with the College of Education to develop a draft disclosure form, policy, and supportive infrastructure, as that college had a wide variety of conflict of interest situations. It was felt that if a policy and procedure could work for the COE, it could be taken to other areas of the university community for further testing and implementation. The COE worked with ORCR through various iterations of the disclosure form and through this process some very complex individual COI-C issues were resolved to everyone's satisfaction.

That testing-implementation process brought about the faculty feedback and the creation of the Ad hoc Senate Committee. The ORCR looks forward to working with the Senate Committee.

Bonine asked for an example of a complex situation. Schenkel said that confidentially prevented explicit discussion of specific COI disclosures at the university. Bonine stated that this is one of his concerns: where and to whom disclosures are made. He mentioned state laws and restrictions on how many personnel files may be kept on an individual.

Linton said that without going into great detail there are categories of issues within the COE – these occur both inside and outside [the institution]. There are enterprises around educational assessment such as learning assessment tools and some of those are very prominently distributed around the country. There is a combination of issues around conflict of interest where there is federally funded work going on and external entities are created out of that work and those [relationships] need to be managed appropriately. Many of the individuals involved are wearing multiple hats in their lives - between their internal activities at the university and their activities

with external entities. That's why many of these are complex – because they combine many of the elements of COI and COC.

Bonine asked what some of the COC issues were. Some public record information was shared. In this case, faculty created educational and measurement tools that first arose, in part, out of federal funding but also, in part, from individual investment. Those tools were utilized for federal programs and their selection and implementation was reviewed. The university's involvement as to whether or not it had policed its own conflict of interest policies and regulations was also reviewed.

Bonine asked what, if any, conflict of commitment issues did or could arise from the development of these tools. Schenkel responded that in many of the complex conflict of interest cases, a component of conflict of commitment, or time away from the University, also arises.

Bonine said he presumed, that for the most part, it's the College of Education that cares about whether people are performing their duties to students and to research, not the research office…that this is a dean's or department head's responsibility to make sure that the faculty are on the job. Linton said that this is the way the process is set up. Schenkel added that as an institution we are required to certify to the federal government that all conflicts of interest certifications and requirements and management of any conflicts of interest are being done.

Bonine said that federal government does not care about conflict of commitment issues or the university's policies in that area.

Tomlin noted that in some of the more publicly visible cases, an associated pattern of professional performance in which a person's participation in the ordinary activities, which a set of peers would expect from one another, was compromised. And in that, we, as an institution, even if we focus at the school and college level, and department level for it's detailed management, none the less have an interest in understanding that our expectations are that individuals on 1.0 FTE commitments are committed with essentially 100% of their professional time to the enterprise that has employed them. We want to find a way to ensure that we are all dedicating the amount of energy that we agreed to together. There are many things that get very thorny here. Tomlin feels there is an interplay between the need for establishing practices that make sense within an existing policy and seeing whether there is continued need for overarching policy to guide that and then how those things are integrated in the end with conflict of interest so that there is a comprehensive treatment of the most complex cases without bringing the complexity needlessly into settings that are handled more simply.

Horner stated that there were three major issues. The first dealt with people doing consulting and how much time one can be gone doing consulting – the key point being: is the faculty member here enough to actually do their teaching and the supervision of the research – but the question is, what is the rule, what is the general guideline for doing that? Second, what is related to publications - books, tools, and data systems – especially computer data systems - and who has ownership and where does the revenue go? Critical to that is the whole notion of spin-off and at what point can the professor set up a non-profit or profit corporation (another entity) and how then is the ownership of the intellectual property and the actual content of the tools balanced? The last really relates to an issue of student involvement in situations where a private corporation is set up. There is a student – professor relationship on one hand and then the professor who also

owns a corporation is hiring the same student to work for the corporation – that is a conflict of interest issue.

Bonine suggested that if the deans failed, if these issues cannot be managed at the dean or department level and it has to be managed down at Riverfront Research Park that means that it has been decided that the way to get this done is to not have it managed at the school level. Bonine stated he could understand that there were errors here, but those errors can sometimes be solved by firing the professor, talking to the dean, firing the dean, coming up with a better policy inside the department. Bonine said the reason he asked all those things is that the law school found the language in the draft policy about textbooks to be quite astounding and that they could not live with all of that, where as in the College of Education it might be quite necessary [to have such language].

Schenkel provided some clarifying language regarding the draft policy on textbooks and Tomlin noted that this is an example of something that needs to be fixed in the draft policy as the university does not have explicitly written contracts.

Brau asked if it was known what fraction of the faculty actually has conflict of interest issues that have to be disclosed. In Horner's estimation, less than 9 people out of 800 (about 1%) in the College of Education needed to submit disclosures. Horner estimated that in the COE, less than 10% of the people would need to go beyond the first four questions of the disclosure.

Schenkel said that the majority of people who have disclosed to date are people that have either spin-offs, or licensing agreements, or involvement with outside entities. A lot of people have also come to ORCR to ask what they need to do.

4. DISCUSSION OF SPLITTING OF COI-C INTO COI AND COC
The Chair suggested that the committee simplify matters conceptually and practically by separating the COI issues from the COC issues. By addressing COI first, this would enable the committee to meet the deadlines of bringing the redrafted policy to the March 2009 meeting of the UO Senate. The COC issues could then be addressed within the following two months. Each committee member was asked to provide their opinion and support or lack of support for this phased approach.

Horner said he didn't have a sense of the scope of the number of issues. If the number of issues in total was less than ten, he felt the committee could approach them [COI & COC] together. He is comfortable with the phased approach, but not with establishing two separate policies.

Linton also supported a phased approach in order to have a recommendation ready for the UO Senate meeting in March. There is a need to have a functional policy everyday, we have disclosure requirements everyday, we've got federal requirements that we are meeting and we have had a policy in place for more than a decade and we need to move those policies and processes forward. We have a joint agreement between the University and OUS to have the COI process in place by July 1. A vast majority of the angst, concern, frustration, lack of understanding, and confusion about the policy is more in the conflict of commitment domain than in the conflict of interest. More time is needed by the institution to define COC. Long term, Linton said he would like to see the integration of COI and COC. However, he was confident that the deadlines could be met by looking at COI first, followed by COC.

Linton also noted that the institution's vulnerability is primarily in the area of conflict of interest, as this is what was noted in the 2006 audit by OUS. The federal requirements are also focused on conflicts of interest and disclosure is required by the Public Health Service, including the National Institutes of Health.

Tomlin was initially interested in keeping COI and COC together, but recognized that COC was the thornier of the two and required a culture change. He acknowledged that there are existing personnel practices that allow some COC issues to be handled. There are other areas which we would benefit from having a general overarching sense of what faculty, as colleagues, expect of each other and in the end formulating a conflict of commitment policy that dovetails with the conflict of interest policy and is comprehensive, as Rob mentioned, will make sense. In this, no one ever imagined and don't hold the position, that it is only the Office for Responsible Conduct of Research that is the vehicle by which this is managed. Some matters must go through the Academic Affairs chain, that pathway from faculty to department head to dean and from dean to Academic Affairs and some of those matters will never cross, for example, Rich's desk at all. There will be other matters that will cross Rich's desk that are not germane to those who work in Academic Affairs. However, to the extent that there is overlap, value has been seen in having a common spot, not just for our convenience, but for our colleagues' convenience – that there would be a pathway that would eventually bifurcate as needed to either Academic Affairs or to Research. Conflict of interest is not restricted to research. The split approach would allow the COC issues to be more carefully examined.

Schenkel is in favor of the phased approach as there are current vulnerabilities in the area of COI for the institution and for individuals.

Brau agreed that at least initially it was best to understand conflict of interest issues and to focus on that area.

Youm said this is the better way to focus on COI. The committee should move from COI, which is easier to handle, into COC, which is over broad, and as Tomlin put it, thornier.

Bonine said he had no problem with dividing [COI & COC] in that way. Given that approach, he asked how input at the Town Hall should be handled. Should the committee listen to and respond to comments about both areas or just COI?

There was a consensus that the Town Hall discussion should be open to both COI and COC issues, as whatever questions or comments the participants have will need to be heard.

Citing concerns about the complexity of the issues, a short time line for the work, and recognizing that there are considerable faculty concerns about COC, there was consensus by the committee to take a phased approach to COI and COC. Starting with COI will allow a more careful examination of the deeper COC issues.

At 4:00 p.m., due to a prior commitment, Tomlin excused himself. The remaining committee members agreed to continue beyond the scheduled meeting time.

5. DISCUSSION OF TOWN HALL MEETING

The committee discussed the format of the upcoming Town Hall meeting on Wednesday, January 21 in 166 Lawrence, 3:00p.m. to 5:00 p.m. This meeting is jointly sponsored by the UO Senate and the UO Chapter of the American Association of University Professors (AAUP).

The executive committee of the UO Chapter of the AAUP and members of the UO Senate ad hoc COI-C Committee will also be present in the front of the room to serve as additional resources.

As moderator for the meeting, Peter Gilkey will provide a brief overview and introductions at the meeting. Carl Bybee, Acting President, University of Oregon Chapter of the American Association of University Professors (AAUP), Rob Horner, and Richard Linton will give brief 10 minute presentations. The meeting will then be opened up for general discussion. It is likely that the number of participants will dictate the structure of the discussion.

While COI and COC will be considered by the committee in phases, comments and questions regarding both COI and COC will be welcome during the Town Hall meeting. The audience will want to know (1) why this is happening; (2) what is the timeline and the process for making contributions; (3) what the committee wants from the participants.

The Chair asked John Bonine to record the input provided by the faculty into two separate lists: one for COI issues and another for COC issues. The Chair asked committee members to submit their own lists of concerns to Bonine. These lists will inform the committee in their work on both COI and COC policies. Bonine asked that his following concerns start those lists:
(1) mandated annual certification of compliance; (2) imposition of rules needed for federally funded research on professors not engaged in federally funded research; (3) confidentiality of internal disclosures; (4) appropriate level of reporting (departmental or centralized); (5) provisions for variability among different disciplines and departments/schools.

6. OTHER MATTERS
Agenda items for the next meeting shall be discussed generally by the committee members prior to meeting adjournment. Suggested agenda items may also be sent to the Chair by email. The Chair will determine the priorities and will set the agendas. The committee recognizes the need to plan future agendas while retaining the ability to be responsive to new information coming to the committee members.

The agenda for the next committee meeting, Friday, January 23, 2009, will include:
> 1.) Discussion of the Town Hall meeting and the issues raised; and
> 2.) Review of a redrafted COI only policy with COC language removed

It was agreed that, as a standard practice, a draft of the minutes will be submitted to the Chair for his review and edit prior to disbursement to the committee members for their approval via email. Once approved by the committee, the minutes will be posted to the UO Senate COI-C Committee web site (http://www.uoregon.edu/~uosenate/dirsen089/COICOCC.html) by the Chair.

WITH NO FURTHER BUSINESS AT HAND, THE MEETING ADJOURNED AT 4:35 p.m.

Minutes submitted by Meg Rowles
Reviewed and edited by Peter Gilkey
Approved by the committee on 1-23-09