

APPROVED - UO Senate ad hoc COI-C Committee Meeting Minutes

Thursday, February 12, 2009, Johnson Hall Conference Room
4:00 p.m. to 6:00 p.m.

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

Non-voting Members Present: Lynette Schenkel
Non-voting Members Absent: Meg Rowles

1. CALL TO ORDER

John Bonine, Chair, called the meeting to order.

2. DISCUSSION OF BIG ISSUES

The committee members agreed that some of the 'Big Issues' would require further research and would be 'bracketed' as items to revisit at a later date. Some of the issues pertained only to state regulations and were set aside for discussion under Phase II of the conflict of interest work by this committee. Phase I is focused on financial conflict of interest as it relates to sponsored research and sponsored programs conducted under external funding.

Each 'Big Issues' item is listed below with the summarized outcome discussed by the committee members. The full text of each item may be viewed at <http://www.uoregon.edu/~uosenate/dirsen089/COICOCC.html>

[Note: As requested by Schenkel, tasks are underlined.]

A.1. Scope is limited to sponsored research

A.2. [state issue - deferred]

A.3. [state issue - deferred]

A.4. [state issue – deferred]

A.5. [state portion of this was deferred]

[As it relates to sponsored research, the Public Health Service regulations (applicable to NIH funded research), covered persons include Investigators, which is defined as the Principal Investigator *and* any other person who is responsible for the design, conduct, or reporting of research funded by the NIH, or proposed for such funding. The definition includes the Investigator's spouse and dependent children.]

Brau felt that this was too inclusive and that only Principal Investigators and Co-PIs should be required to disclose. He also stated that graduate students should not be included as covered persons. Schenkel and Bonine both noted a recent site visit by NIH to University of North Carolina at Chapel Hill and the NIH suggested that their 'covered persons' list be expanded to be more inclusive rather than less inclusive. Brau and Schenkel will research this further and report back to the committee.

B.1. Information requested on COI disclosure forms will be limited to what is required to meet legal requirements.

B.2. Bonine stated that it was true that academic and personal freedoms could be imperiled with reporting requirements that are more broad than necessary.

B.3 [deferred]

C.1. While there is no legal requirement for annual disclosures, it was noted that the UO may want to do this and that most universities have an annual disclosure requirement.

C.2. [deferred]

C.3. [deferred]

D.1. The committee asked that General Counsel be asked for their opinion on this issue. Schenkel may have some documentation on this matter – she will report back to the committee.

D.2 The committee agreed that information disclosed on COI forms should remain confidential to the extent that it can be done [under existing laws]. Reference was made to Stanford's confidential statement on their form (just above the signature). Linton noted that there is a need for guidance from General Counsel but that in principle the fact that a disclosure has been made could be made public, but not the details of the disclosure.

D.3. The committee agreed that guidance from General Counsel was needed on this issue.

D.4. The extent of the University's computer security measures, etc. is unknown. Schenkel noted that where ORCR controlled the process, the disclosures were hand-delivered and were [are] kept in locked files. The planned electronic submission program has several access security checks, etc. but due to budget constraints, purchase of that software has been deferred. Schenkel will provide copies of the ORCR SOP that addresses handling of the disclosures.

The committee briefly discussed disclosures made via paper v.s. on-line submission and the potential of exposure with either method. Bonine stated that whatever the level of security is, it should be communicated to the individuals completing the disclosure.

[The newest draft policy is based on paper disclosures.]

Bonine offered to follow-up with General Counsel on items D.1 through D.4.

E.1. [deferred] Briefly, Schenkel noted that ORCR served as a central depository, but it is not required and could be handled by the departments. All agreed that simplicity is important.

E.2. The committee agreed that a single, uniform policy is preferred and is compelled by federal regulations.

F.1. It was noted that the \$10,000 and 5% thresholds were required by federal regulations and should be the standard, except where there is invasive human subject research (use of drugs or

devices is involved). For such human subject research, any financial interest is the standard threshold for disclosure. The 49% of 1.0 FTE is not a federal research threshold – Bonine will follow-up with Horner on the origin and desire for this element.

F.2. Schenkel referred to Stanford’s policy statement (Page 6, Section 5, Paragraph 3). [Note: this paragraph explains what is and is not considered an “invention” by Stanford.] A closer look is needed at both Stanford and University of Indiana language and at Oregon law to see what might be exempt from disclosure under the COI policy. [ORCR to extract the applicable pieces for comparison by the committee.] It was noted that it would be impossible to list everything that might be excluded, but departments should be asked to look carefully at this section of the draft policy. [It was noted that this issue also extends into the state regulations and that portion of the discussion will be deferred.]

G.1. NIH regulations requires disclosure at the time of application for funds, review must occur and approved management plans (if required) must be in place prior to the expenditure of NIH funds. Bonine noted that this needed to be explicitly stated in the policy. [This may be different from requirements on state related issues – which was deferred]

G.2. Bonine suggested that if an individual were to make an appeal to the outcome of a COI disclosure review or management plan, they should be able to nominate another faculty member to serve on the COI Committee for the express purpose of reviewing their particular case. Schenkel will provide language to look at for both the policy and the COI Committee Charter.

G.3. [deferred]

G.4. Schenkel will provide the committee with some examples of management plans. This is a challenge, as plans are unique to the situation.

G.5. [deferred] See G.2.

G.6. [deferred] Same as disclosure – See D.1. through D.4. Bonine to obtain guidance from General Counsel. [state portion deferred]

H.1 Houm will research further and report back to the committee.

I.1. Brau will provide the committee with alternative definitions. The committee members agreed that the definitions should be simply and not include statements of policy. These will be looked at carefully by the committee when the draft policy document is reviewed.

J.1. Consultation with OTT, ORSA, OPHS, and OVSAC with regard to their roles and responsibilities under this policy will be facilitated by Rich Linton once the draft has been prepared by the committee.

J.2. No longer relevant, as any individual seeking external funding for research will be included in the roll out of this policy.

J.3. Education and training are not part of this committee’s charge.

J.4. [deferred] Bonine asked if an explanation of coverage could be illustrated in a table or flowchart.

3. APPROVAL OF THE MINUTES

The 2-4-09 meeting minutes, with one correction, were approved.

THE MEETING ADJOURNED AT 5:00 p.m.

Minutes recorded by Lynette Schenkel

Minutes transcribed and submitted by Meg Rowles

**Web page spun on 26 February 2009 by Peter B Gilkey 202 Deady Hall, Department of Mathematics at the University of Oregon, Eugene OR 97403-1222, U.S.A. Phone 1-541-346-4717
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