

Minutes*

**Senate Consultative Committee
Thursday, February 14, 2013
3:00 – 4:00
Room 238A Morrill Hall**

Present: Sally Gregory Kohlstedt (chair), James Cloyd, Nicole Conti, Will Durfee, Ann Hagen, Joe Inhofer, Russell Luepker, Adam Matula, Cynthia Murdoch, Amy Olson, James Pacala, Jeff Ratliff-Crain, Rebecca Ropers-Huilman, Thomas Sondreal, Moshe Volovik

Absent: Ben Baglio, Avner Ben-Ner, Peter Bitterman, Brandon Breuer, Chris Cramer, Nancy Ehlke, Gyaltsso Gurung, Michael Hancher, Elaine Tyler May, Alon McCormick, Richard Ziegler

Guests: Jon Guden, Lynn Zentner (Office of Institutional Compliance)

Others: Sarah Dirksen, Ken Savary (Office of the Board of Regents)

[In these minutes: (1) Institutional Conflict of Interest policy changes; (2) statement on possible expansion of the Big Ten Conference; (3) docket approval; (4) administrative costs]

1. Institutional Conflict of Interest Administrative Policy Changes

Professor Kohlstedt convened the meeting at 3:00 and welcomed Mr. Guden and Ms. Zentner to discuss proposed changes to the Institutional Conflict of Interest (COI) administrative policy.

Mr. Guden began by explaining that there are at present six separate procedural documents associated with the Institutional COI administrative policy; those are being combined into one. The policy itself is being revised because of changes to the corresponding Board of Regents policy on institutional COI; these changes ensure the two policies align. The policy also has not been reviewed for several years; given the experience with it, it needs updating.

They also decided that the policy needs to address two special areas, Mr. Guden reported, University Interests and Related Transactions and Human Subjects Research Involving More than Minimal Risk. The pertinent language:

University Interests and Related Transactions

The Conflict of Interest (COI) Program will review annually reports of University royalty earnings, gifts, purchases, and industry sponsored research projects to evaluate whether any institutional conflicts may arise from these interests. The COI Program will refer potential institutional conflicts of interest to the Institutional Conflict Review Panel for review and action. The University relies on the separation between its investment decisions and research activity to effectively manage any potential conflicts related to investment holdings.

* These minutes reflect discussion and debate at a meeting of a committee of the University of Minnesota Senate; none of the comments, conclusions, or actions reported in these minutes represents the views of, nor are they binding on, the Senate, the Administration, or the Board of Regents.

The General Counsel will assess whether there is potential for an institutional conflict of interest prior to entering into substantive discussions or making an oral or written commitment regarding a commercial transaction that has a value greater than \$2M, appears to have a significant impact on the University's mission or raises unusual questions of public interest or public policy.

The COI Program will refer those matters that meet the criteria for Board of Regents (Board) approval under Board of Regents Policy: *Institutional Conflict of Interest*, to the Board for review and action.

Human Subjects Research Involving More than Minimal Risk

When a department within the University proposes to evaluate a technology in which the University has a financial interest, and the evaluation is determined by the Institutional Review Board to involve "more than minimal" risk to human subjects, the COI staff and Executive Panel will gather information for consideration by the full Institutional Conflict Review Panel. In assessing and managing potential institutional conflicts of interest involving human subjects research, the Institutional Conflict Review Panel (ICRP) presumes that the research should not be conducted at the University unless there are compelling circumstances that justify proceeding with the research here despite the institutional conflict. (See Administrative Procedure: *Reviewing and Managing Potential Institutional Conflicts of Interest: Special Situations*)

Mr. Guden also noted for the Committee the administrative procedures that accompany the administrative policy, and he highlighted the language covering human subjects and mission-related commercial transactions.

II. Special Situations

A. Human Subjects Research Involving More Than Minimal Risk

1. When a department within the University proposes to evaluate a technology in which the University has a financial interest, and the evaluation is determined by the Institutional Review Board to involve "more than minimal" risk to human subjects, the COI staff and Executive Panel will gather information for consideration by the full Institutional Conflict Review Panel.
2. In assessing and managing potential institutional conflicts of interest involving human subjects research, the Institutional Conflict Review Panel (ICRP) presumes that the research should not be conducted at the University unless there are compelling circumstances that justify proceeding with the research here despite the institutional conflict.
3. The ICRP may approve conducting the research at or under the auspices of the University if it determines, based on a fact specific inquiry, that compelling circumstances are present, and that an effective conflict management plan can be implemented to protect the welfare of human subjects and the integrity of the University's research. Whether the circumstances are "compelling" will depend in each case upon an analysis of:

- The nature of the research, including current phase of development and intentions for subsequent phases;
- The nature of the financial interest;
- The degree to which the University and its employees stand to benefit financially from the research;
- How closely the financial interest is related to the research and the degree to which the financial interests may be affected by the research;
- The degree to which the conflict can be effectively managed;
- The magnitude of risk to human subjects inherent in the research and how those risks may be affected by the institutional conflict; and
- Whether the University is uniquely qualified, by virtue of distinctive resources (e.g. special facilities or equipment, unique patient population) and the experience and expertise of its investigators, to conduct the research and appropriately safeguard the welfare of the human research participants involved.

4. If the ICRP approves conducting the research at the University and determines that a CMP is required, it will coordinate its work with the Institutional Review Board (IRB), which has final authority to determine whether the CMP adequately protects research subjects such that the research may proceed.

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D. Mission Related Commercial Transactions

1. The General Counsel will assess whether there is potential for an institutional conflict of interest prior to entering into substantive discussions or making an oral or written commitment regarding a commercial transaction that has a value greater than \$2M, appears to have a significant impact on the University's mission or raises unusual questions of public interest or public policy.
2. If the General Counsel determines that the transaction may compromise or appear to compromise the University's research, teaching, or outreach mission activities, or its institutional reputation, the General Counsel will inform the appropriate executive decision-maker and the Director of the University's Conflict of Interest Program and refer the matter to an ad hoc committee for review.
3. The ad hoc review committee, assembled by the General Counsel, will consist of relevant academic and administrative officers, identified by the President or his designee, and one or two members of the University's Institutional Conflict Review Panel, as recommended by the Chair of the Panel. The committee will identify issues that need to be considered in the decision-making process and offer a perspective on those issues. The input of the ad hoc review committee will be advisory in nature, and not binding.
4. The General Counsel and the appropriate executive decision-maker will share the input of the ad hoc review committee with the President and determine how to proceed, subject to a final decision by the President or the Board pursuant to Board of Regents Policy: *Institutional Conflict of Interest*.

The procedural language about human-subjects research is modeled on a recommendation from the Association of American Medical Colleges (AAMC), Mr. Guden reported, modified to fit the University. In large part, the point of the language governing commercial transactions is to avoid harm to the University's reputation.

Ms. Zentner explained that in the case of human-subjects research, the AAMC policy contains a rebuttable presumption: The presumption is that the institution should not permit the research to take place in one of its departments when it has a financial interest in the outcome of the research. However, that presumption can be rebutted. They looked at policies from a number of higher-education institutions and have drawn on provisions in those policies in drafting the proposed language in the revised procedure that is now undergoing review. This policy and the procedures trigger a careful look, using the criteria outlined in the procedures. If the decision is that the research may remain at the University, then a conflict-management plan must be developed before the conduct of the research begins. Former Vice President Mulcahy approved the plan, as has Mr. Schrankler in the Office for Technology Commercialization and Vice President Herman. President Kaler has indicated he is comfortable with the proposal as well.

Professor Kohlstedt noted that the Senate Research Committee had reviewed and approved the proposals as well.

Professor Durfee offered three comments. One, in the language concerning human subjects research, the term "technology" seems too narrow; does it cover everything they want the policy to cover? Two, apropos of the language "the magnitude of risk to human subjects inherent in the research and how those risks may be affected by the institutional conflict," risks are inherent in such research but it is not clear they are affected by COI or how they are affected by it, although one can see that there may be a trade-off between the two. Three, apropos of the language "whether the University is uniquely qualified, by virtue of distinctive resources (e.g. special facilities or equipment, unique patient population) and the experience and expertise of its investigators, to conduct the research and appropriately safeguard the welfare of the human research participants involved," it seems to imply that if one receives an NIH grant, for example, the intent is that the COI committee could say that another PI at another university could do the research, so the grant should be turned down.

Ms. Zentner said they would look at the term "technology" to see if another term should be substituted or if a definition of "technology" would help. She said that the Institutional COI Panel makes no determination about the level of risk to human subjects; that is determined solely by the IRB. The Conflict of Interest Program and COI panels do not weigh in on this issue at all. Once the IRB reaches a decision on this issue, they convey that determination to the COI Program which is then shared with the Institutional COI Panel. On the third point, they make every effort to see if the PI at Minnesota is uniquely qualified to do the research; if not and there are no other compelling reasons to conduct the research here, that COI panel would likely decide that the research should not be done here. She said she did not know if that would mean declining the award; the thought was that another PI at another institution would pick it up. Several Committee members pointed out that transfers of grants do not happen.

Professor Cloyd asked the guests if they had any sense of the frequency with which an inventor at Minnesota invents something that is then shipped elsewhere for development. It has not happened as far as she knows, Ms. Zentner responded, at least not during her five years at the University.

Professor Cloyd suggested that the word "presumes" in the language "In assessing and managing potential institutional conflicts of interest involving human subjects research, the Institutional Conflict Review Panel (ICRP) presumes that the research should not be conducted at the University. . . "is pejorative and tells the committee how it should lean unless proven otherwise. He said he believes they are doing the right thing in crafting the policy but suggested they should reconsider the word "presume." It could be that a faculty member invents/creates something unique and there is no other place and no one with the same passion who will develop it. The language provides a disincentive to do the research, Professor Durfee added.

Professor Cloyd next asked if they have a timetable of response metrics. They do not in connection with the evaluation of individual conflicts of interests nor in connection with institutional conflicts of interest, Ms. Zentner said, and they take the time necessary to fully address the circumstances. Under the new Public Health Service regulations that went into effect in late August 2012, COIs associated with PHS funded research must be disclosed to the Conflict of Interest Program via a REPA within 30 days; if there is to be a COI management plan, it must be developed within 60 days. Such timing requirements do not apply to research that is not sponsored by a PHS agency nor to COIs that need to be evaluated in circumstances other than those involving research. Delays can occur in connection with getting all relevant information collected, circumstances may change, etc., or because of the volume of matters the COI Program is addressing at any particular point in time, e.g., within the weeks immediately following REPA filings. There are many variables that play into timing and that will not change under the revised policy. The individual COI panels meet monthly (the Institutional COI committee less often if it has no matters to take up); if there are time pressures, an interim management plan could be developed that would then be presented to the COI committee for final approval. Professor Kohlstedt said that since Ms. Zentner has been director of compliance, timing issues have become less of a problem.

Professor Luepker echoed Professor Cloyd in saying that timely evaluation is helpful. He asked what happens once there is a conflict-management plan established; who is responsible for the oversight? Is it passed to the IRB to check up on? What is the mechanism to check on conflict-management plans? Ms. Zentner said the plans are monitored by the COI program, which is her office, not the IRB. They stay in touch with individuals subject to a management plan to ensure compliance with it. Staff of the COI Program follow up with the individual who is subject to a plan 90 days after the plan is in effect to determine if all elements of the plan have been complied with. Once confirmation of compliance with the plan is received, monitoring of the plan is done annually as long as the plan is in effect. Once the circumstances that required the plan no longer exist, the plan can be retired.

Professor Kohlstedt asked the Committee if it wished the policy changes to go to the Senate, assuming there is a definition of "technology" added. Professor Cloyd repeated his query about the use of the term "presumes" and asked if there is not a better phrase. Ms. Zentner said they raised the question of the presumption with both vice presidents for research and the president and all were comfortable with it. Mr. Guden said that at the individual level, if a PI has a significant financial interest in research on human subjects with more than minimal risk, that PI cannot conduct the research but the research likely stays at

the University and another PI assumes responsibility. These circumstances have not arisen at the institutional level to date.

The Committee voted unanimously to endorse the policy changes.

2. Statement on Possible Expansion of the Big Ten Conference

Professor Kohlstedt asked Committee members to review the statement that had been adopted by the Advisory Committee on Athletics (ACA) and the Faculty Academic Oversight Committee for Intercollegiate Athletics (FAOCIA) and asked if the Committee wished to endorse it. She noted that the two committees had developed the statement after the last expansion to include Maryland and Rutgers, when the process moved very quickly. The statement suggests guidelines that should be followed in any future expansion discussions. The statement read as follows (between the * * *):

* * *

Statement on Conference Expansion

The Advisory Committee on Athletics (ACA) and the Faculty Academic Oversight Committee on Intercollegiate Athletics (FAOCIA) understand there is a strong possibility of further expansion of the Big Ten Conference and that there may be no time for campuses to consult. Given that possibility, we believe these issues should be considered carefully before a decision is made about extending an invitation to an institution to join the Big Ten Conference:

1. A new institution must match the academic emphasis of the Big Ten. It is imperative that the academic standards and credentials of an institution reflect the academic quality of the University of Minnesota and members of the Committee on Institutional Cooperation (CIC).

Institutions under consideration should:

- Be Associate of American Universities (AAU) members
- Place a strong emphasis on academic excellence
- Have robust research and scholarship programs
- Demonstrate strong graduation rates

2. A new institution must match the athletic culture of the Big Ten.

Institutions under consideration should:

- Value student-athlete welfare above athletic success
- Maintain high Academic Progress Rates (APRs) throughout all athletic programs
- Have a culture of compliance and a vigorous Athletic Compliance Office
- Provide strong academic support to student-athletes
- Demonstrate a commitment to institutional control as described in the Freeh Report and is being considered by the Big Ten

3. Financial benefits of expansion proposals should be conservatively evaluated.

- Potential benefits should be rigorously scrutinized by independent experts
- Financial benefits should not jeopardize the education of student-athletes—for example, increasing travel days for student-athletes from expanding mid-week games at the behest of television networks

4. Equity and diversity – An institution considered for expansion should match the University of Minnesota's commitment to diversity and to equity for women and to non-revenue sports.

5. The wellbeing of student-athletes should be a primary consideration. Even minor points can have large effects. For example, a small increase in flight duration can necessitate an earlier departure, resulting in more missed classes.

6. Consult as broadly as possible before agreeing to expansion. Given the complex impacts of expansion, the President should make use of those faculty and staff with extensive experience with Athletics, including members of the Athletics Department and the relevant governance committees.

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Professor Luepker commented that if these are to be the criteria for future expansion, what happens if they are not met?

Professor Cloyd asked if the University of Minnesota met these criteria. Is this a case where the University says anyone new must be as good as it is—and then others say that "we have problems in our own house"?

Professor Ropers-Huilman said she very much liked the document. The last time the process went so fast that the committees read about it in the newspapers. This document provides a set of criteria that President Kaler can bring to discussions at the Big Ten if there is further discussion about expansion. It is good to have something on the record.

Mr. Volovik said he did not know if these criteria were the University's values; they are the values set forth by the two committees. Professor Kohlstedt said that this Committee is the umbrella committee; it must rely on Senate committees to do their work and cannot redo all that they did. The Committee must trust that these are two committees that have done their work well.

What is the utility of the statement, Professor Pacala asked? "Just to make us feel good about ourselves?" If it had been passed in the past, then the president could have agreed that Maryland and Rutgers could join. What does this do?

Mr. Matula said that the larger point is about consultation, not that this is an enforceable document. It asks for consultation in the future.

Professor Kohlstedt said that the document puts on record matters that the president should respond to; it does not purport to give committees more power.

The Committee voted 11-1, with one abstention, to endorse the statement.

3. Docket Approval

Professor Kohlstedt reviewed the short University Senate docket; the business portion of the meeting will be short because the president is giving the State of the University address. The Committee approved the docket without discussion.

4. Administrative Costs

The Committee held a discussion of administrative costs at the University. The discussion included the job families reorganization, the sometimes publicly negative discussions of the work of P&A and Civil Service staff, the question of "too many administrators," the potential implications of market comparisons, faculty reliance on staff, job classifications, the "spans and layers" analysis, and the need to address anxieties while the various studies and changes take place.

It was agreed that the Committee would develop questions for Vice President Brown about the job families reorganization and ask her to join a meeting in the near future.

Professor Kohlstedt adjourned the meeting at 4:00.

-- Gary Engstrand

University of Minnesota