

Minutes*

**Senate Research Committee
Monday, February 6, 2012
2:15 - 4:00
238A Morrill Hall**

- Present: Linda Bearinger (chair), Alvaro Alonso, Melissa Anderson, Margaret Catambay, Jerry Cohen, Marc Dunham, Greg Haugstad, Seung-Ho Joo, Frances Lawrenz, Tucker LeBien, Jennifer Linde, Randy Moore, Kola Okuyemi, Federico Ponce de Leon, Thomas Vaughan, Karen Williams, Lynn Zentner
- Absent: Arlene Carney, Anna Clark, Paul Cleary, Robin Dittman, Demoz Gebre, Maria Gini, Timothy Mulcahy, Christopher Nappa, LaDora Thompson, Alexander Thorkelson, Kyla Wahlstrom
- Guests: Professors Arthur Erdman and Michael Oakes (conflict of interest committees); Associate Vice President Pamela Webb (Sponsored Projects Administration); Russell Straate (Associate Director, Venture Center)
- Other: Emily Lawrence (Office of the President)

[In these minutes: (1) statement on research; (2) conflict of interest and faculty entrepreneurship]

1. Statement on Research

Professor Bearinger convened the meeting at 2:15 and reported that she had carried the Committee's statement on the value of research to the Faculty Consultative Committee. The statement was well-received and the discussion focused on how it might be used.

2. Conflict of Interest (COI) and Faculty Entrepreneurship

Professor Bearinger welcomed Professors Erdman and Oakes back to the Committee to join Ms. Zentner in a continued discussion of the perceived tension between (1) the University's stance and policies on conflicts of interest (COI) and (2) faculty entrepreneurship and involvement in translational research. She reviewed the issue as it had been raised and discussed thus far.

The Faculty Consultative Committee asked this Committee to take up a suggestion it had received from a faculty member:

Translational research is a heavily promoted topic at the UMN, NIH and NSF. The UMN publically encourages faculty to engage in translational research and to work with industry to make faculty discoveries available for the benefit of the public. The U of MN has a large translational research institutional grant. The success of the thrust for translational research is endangered by an alarming, expanding UMN administrative mentality that faculty who seek to

* 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.

develop, perfect and commercialize their research discoveries have a conflict of interest (COI) and must prove innocence before improper activity occurs. There seems to be an obsession to stamp out even a remote possibility that an action of faculty might be interpreted by the news media, public, government agency or others as arising from a COI. Perhaps this is a holdover from our experience as a NIH "exceptional" institution or highly publicized instances of accused excessive compensation. I ask if all of this activity about what might happen a positive stimulus for encouraging faculty to perform translational research? Should we not step back and review this process?

Recent COI committee decisions imply that when the UMN Office for Technology Commercialization (OTC) decides not to patent and commercialize a faculty member's invention those faculty who proceed to develop, test and eventually see their product to market, while holding an active appointment, have a COI. Does this suggest that faculty should not perform research that will benefit them, directly or indirectly or that might benefit any business entity, especially one in which they themselves or a relative are associated? This attitude can have a chilling effect on translational research.

All researchers are biased toward the products of their research. It is a natural and necessary effect of the zeal necessary to perform meaningful research. It follows that most faculty have an inborn COI, even when communicating their results. But must researchers be suspected of improper bias or improper reporting of their research results to either benefit their discoveries, their self-esteem or their reputation? With such self interests should they be permitted to be the Principle Investigator on grant proposals? A yes answer implies that their work and publications should be monitored. But are not such attitudes contrary to the principles of professionalism, of academic freedom and to fulfillment of the aims of translational research?

This is the second discussion focused on the topic, Professor Bearinger noted; following the December 5 discussion she had asked Committee members to think about the questions that were raised. Several points were made in the December 5 discussion:

-- Professor Vaughan made the point that as a land-grant institution, the University is committed to serving the needs of the state and working with industry and so on while also abiding by federal COI rules. This commitment to "Encouraging faculty innovation and entrepreneurship" was made by 140 university presidents, including President Bruininks, to Secretary Locke of the U.S. Department of Commerce in a letter entitled "Recommendations to Facilitate University-Based Technology Commercialization, April 2010."

-- NSF and NIH are heavily promoting translational research. There has been much national support for innovation and entrepreneurship, streamlining reporting, and the like; a national statement called for not inhibiting innovation and entrepreneurship, and President Kaler has talked about getting research results into the marketplace.

-- There is a sense among some that the University takes the position that there is a conflict of interest until someone proves otherwise. Professor Vaughan said the COI committee is doing three things to minimize COI: It is decoupling faculty from leadership of a company. It is disallowing compensation, and requires faculty to reduce their equity to less than 5% for biomedical startups. His point was that if the University does not allow effective involvement in a start-up, it takes away the initiative and

entrepreneurship. Professors Feeney and Oakes said the University must create a firewall between a company and a faculty member who also holds a federal grant that might involve work that would benefit the start-up company. The two roles—faculty member and entrepreneur—must be reconciled, and Professor Oakes described changes that have occurred in the past six months that allows for more active faculty involvement in the developmental stage of a start-up.

The ultimate issue before the Committee, Professor Bearinger concluded, is whether it wishes to make a statement of some kind to present to FCC.

Professor Alonso asked how many of the regulations are federally-imposed and how many has the University decided to adopt on its own. If most are the former, there is not much that can be done. In addition, how do regulations at the University compare with those at its peers?

Ms. Zentner explained that the federal rules have been in place since 1995. The University could have said that it would only apply them to Public Health Service researchers, but it decided to adopt them institution-wide. The rules set dollar levels for COI; if one reaches the level, there is a COI. This is not a bad thing; the question is about managing the conflict. Under NIH rules, if there is a COI, the individual must reduce, eliminate, or manage it (if one has a grant that results of which could further the interests of the company). Doing so involves reducing payments from a company, reducing one's equity ownership, or stepping back from any leadership role.

What has changed over time: The University had certainly guidelines that were seen to inhibit entrepreneurship, Ms. Zentner said, and they have been changing. It has revamped its policy on COI and interactions with industry, policy changes that were approved by the University Senate. It has also adopted a more restrictive policy for those who are involved in clinical care. Now there is a new rule from the Public Health Service, and this time the University has decided to apply it only to researchers who have grants covered by the rule.

As for peer institutions, each has a slightly different take on the rules, Ms. Zentner said, but they move along similar lines. The University has been a leader in terms of not focusing solely on the Medical School but on the institution as a whole.

Professor Oakes said that the federal regulations basically say to institutions, "solve this" problem of COI. It is up to the institutions to do so. The University has evolved in terms of how it solves the problem and there is always room for interpretation. It wants energy to go into innovation and entrepreneurship—and it does not want to see its mission undermined by scandal. They work with Mr. Straate to manage conflicts and find themselves on the cutting edge in terms of thinking about these issues. But there is no simple answer if the institution is going to follow federal regulations.

Professor Erdman said the problem is three words: conflict of interest. The phrase seems like one who has a COI is in chains and ready to go to jail. Being in a potential COI situation is not as bad as it sounds. It means that one is involved in translational research and likely attempting to take technology out of the University, which is a good thing. The COI committees work at trying to manage or reduce these potential conflicts.

Ms. Zentner added that one of the most important things they try to do, that takes a lot of time, is not just look at a report and issue a conclusion but look at the consulting relationship with the company

and at the NIH grant. They contact people and gather information and have a full discussion. She pointed out that her office does not make the determination, the COI committee, a faculty committee, does so. When there is a COI, they draft a plan that must be approved both by the committee and the individual.

One positive development, Professor Erdman reported, is that more people are coming to the COI committees before things get started. Mr. Straate's group sends people to the committees before things get too far along with a venture capitalist and selecting a CEO and the like so that they think about the issues in a timely way.

Ms. Zentner asked if Professor Alonso is inquiring whether the University is more restrictive than its peers. In the end, yes, Professor Alvaro said; is it more restrictive because it wants to be safe? Professor Bearinger said she inferred from Professor Oakes' comments that the University is not more restrictive and that it depends on how institutions operationalize the rules. President Kaler's question is whether there is a way to operationalize them so that they are less stringent in order that they do not inhibit innovation and entrepreneurship while still protecting the University. That is the balance, Professor Oakes agreed.

Professor Vaughan said he was all in favor of conflict management and fully recognizes the need for it. He continues to believe, however, that in addition to the COI committees there also needs to be a "pursuit of opportunity" committee. There has been considerable focus at the University on its level of risk aversion; the easiest way to avoid risk is to do nothing, but that means missing opportunities. He said he would rather hear discussion about the risk/benefit analysis. There are federal regulations and there is also a mandate to pursue and promote incentives for faculty entrepreneurs. He said he would like to see more emphasis on and pursuit of the entrepreneurial side of things. He listens to the words promoting faculty entrepreneurship from the federal government and from the leadership of the University, tries to start a company, and then is told he can't lead it, can't get paid by it, and can't hold much equity in it.

Professor Oakes said that has changed in the last year. Professor Vaughan responded that Ms. Zentner has said that conflicts must be managed but that one cannot accept a Small Business Grant (SBIR or STTR) to support a PI to translate technology unless one gives up a company (reducing equity ownership to under 5%). One of the issues that arise is a company that uses human subjects in research, Mr. Straate commented. He said he has not seen many COI problems in the last year, but when there are human subjects involved, the University is very risk averse.

A large part of what the University, the Twin Cities, and the state have to offer is biomedical technology, Professor Vaughan responded. It is not a small thing to say that rules only apply to biomedical/health sciences research when much of that work involves human subjects. He cannot participate in a company he started and many of his colleagues feel the same way—they do not feel that they have incentives to be entrepreneurial.

Professor Bearinger said she liked the idea of a "pursuit of opportunity" committee. She said she has the sense that faculty members feel that they are on their own until they start to get successful in starting a company, and then they encounter people who want to manage conflict—and they encounter human-subjects regulations. What statement could be made in favor of entrepreneurship, not just about restricting what faculty members are doing.

Professor Cohen said he hears a lot of discussion about meeting the federal mandate, and SBIR and STTR research are federal mandates where the research has been reviewed by the federal agency. Then one hears that the University is averse to doing research that the federal agency has mandated, that it has offered money to do, and that it has reviewed and approved. He said he cannot understand why the University would not do such research. That seems contrary to all that is also talked about. The University should have a mechanism to make these things happen.

Who at the University is saying "no," Professor Moore asked? Not the IRB or the COI committee, Professor Oakes averred. It is the COI and IRB, Professor Vaughan reported; one must be in compliance with COI rules or one cannot obtain IRB clearance to accept a grant for a company. So the mechanisms do not work at the University, Professor Alonso said. Professor Vaughan repeated that he has been told that the University is very strict with regard to human-subjects research and ownership in a company. That is not the case, Professor Oakes said. There must be some paper trail, Professor Moore said, some charge to a committee, and there should be channels. Ms. Zentner said that NIH, STTR, and SBIR allow exemptions during phase 1. Phase 1 is exploratory, phase 2 is active research, and phase 3 is product development, Professor Cohen said, which is different from medical research. One is exempt from COI rules during phase 1, Ms. Zentner repeated, but there can be an assessment; a college may ask her office to do a COI review. So where is the "no" from Professor Bearinger asked? Ms. Zentner's office? The chair of one's department? No one says that someone cannot have a company. The COI groups ask how a conflict will be managed, and with human-subjects research there is greater risk so there are greater protections needed. What they often say when research with human subjects involves more than minimal risk, the person needs to find a lesser role with the company. Or not be the PI on the grant if one wants to retain a greater share in the company or a greater leadership role, Professor Bearinger added.

But it is not in NIH's interest for the faculty member to give up the PI role, Professor Vaughan objected. That person is the expert and that person committed to and responsible for the leadership role in the grant. To apply for and receive a grant in the name of one PI and then to transfer the grant to another PI who was not peer approved for this work is a sham. Professor Cohen agreed. No one denies the person wrote and submitted the grant; if one were told he or she could not serve as the PI, there would be an ethical question about who gets credit for someone's intellectual work. The University says that because it involves entrepreneurship and also financial interests, it needs to be looked at carefully. That is asking someone to put in intellectual effort and then transfer it to a third party. That cannot happen, Professor Oakes said.

It sounds like the way the rules are explained, Professor Okuyemi said, one is not allowed to proceed with a company unless one is not going to be the PI or gives up the interest in the company. That is a huge disincentive and the rules need examination.

Professor Cohen said that where he and Professor Vaughan had been in conflict is not about the balance between COI and entrepreneurship but about the third leg, which is public perception. He said he does not believe that changing the PI on a grant gives the public the perception that all is OK. No one will believe the University is doing right just because of a change in PIs. Professor Bearinger asked if there was an expectation that PIs would give up grants to keep their companies when the policy was first adopted in 1995. Professor Cohen said that some universities have a mandate for faculty members to run companies. The question is ownership level, Dean Ponce de Leon said. Above 5%, one needs to choose to be either a professor or a CEO—that is the dilemma. In the research lab it is difficult to untangle

whether particular research is providing personal benefits to the researcher or benefits for the common good.

Dean LeBien said that when one is a PI on an NIH grant and involved in a start-up company, the policies make one give up the company or give up the grant. Has anyone ever given up the NIH PI role? (They have, Ms. Zentner said.) Does she have any idea what happened, Dean LeBien asked? Did the company do well and did the grant work still get done. Or was it just a paper transfer, Professor Okuyemi asked? Professors Erdman and Oakes said that the COI committees ask questions and would not accept a paper transfer, i.e., token PIs are not an acceptable solution. The grant would have to be taken by a colleague who had no involvement with the company.

Committee members discussed with Ms. Zentner the role of technical advisor to a company, whereby the faculty member can retain the PI role. That role is seen as more desirable for several reasons. The Committee also discussed the extent to which there is basic research with human subjects that does not involve anything beyond minimal risk.

Mr. Straate explained the approach that has been taken by The Venture Center to equity ownership and conflict of interest. Most of the time equity in a start-up company has very little value; someday it might, but not at the beginning. Companies go through fund-raising, the value of the faculty member's equity is diluted, and investors often require a vesting plan (the faculty member does not own all 40%, for example, immediately), so they look at the vesting plan and equity dilution and perceived value. Most faculty members would be lucky to get 5% when they cash out because there is a lot of dilution over time.

For SBIRs and STTRs there is a new program for faculty: They can own 51% and the University will own 49%, and they work to reduce any conflict with a detailed management plan (this approach will work only for companies that are not involved in research that has more than minimum risk for human subjects). They are glad to have these programs but they struggle with companies that are engaged in work with human subjects that goes beyond minimal risk.

Professor Erdman returned to Professor Cohen's point about public perception. Once in a while human-subjects trials go terribly wrong. One prays that will not happen, but if the public learns that a PI owns the company where something went wrong, the University would have a big problem. He noted that he runs a center on innovation and wholeheartedly supports faculty entrepreneurship. It is management, not prohibition, Professor Cohen said. There is strong review of human-subjects research in federal grants, so that is covered; one can ask if a company is doing the right things but he said he does not see any more risk of doing such research at a company than on a campus. The question is whether an activity rises to a higher level of oversight when it has already received careful review by federal agencies.

Professor Vaughan said there is also a need for the promotion of favorable public perception when the University supports faculty members creating companies that create more jobs and improve the quality of life. It is possible to provide incentives to encourage faculty entrepreneurs and to manage conflict rather than forcing the choice of whether to remain on the faculty or to leave to become an entrepreneur. Why cannot a faculty member have a company and a grant and all the oversight the University wants, including open books, notebooks, etc.? Surely there must be a way to support faculty entrepreneurs. He said he would like to find a solution to manage the perception of conflicts and provide

incentives. This is what the federal government wants and the universities have committed to (e.g., the letter from university presidents to Secretary Locke).

Professor Okuyemi wondered if it would be possible to devise a mechanism that would put issues before the COI committees while a grant application is pending. That would mean the faculty member could be ready if the award is made. Professor Erdman said the COI committees would invite that role and are seeing more and more such requests. during a recent meeting with the COI chairs and co-chairs, President Kaler embraced A better communications plan to convey recent changes related to COI committee views on company start-ups based on productive meetings with members of the Office for Technology Commercialization and The Venture Center. Professor Erdman said that he liked Professor Vaughan's idea of an innovations committee to talk proposals through early in the process.

Professor Bearinger said she heard in this discussion a request for greater clarity around how University policies come to be as well as how to adjust and enhance the methods for implementing federal policies. She also heard suggestions about where the processes might be improved, such as getting support when a grant goes in. There is also a need to improve communication policies. It also appears that there are groups moving toward more tailored approaches to COI. In terms of the innovations committee, she said she could understand how faculty feel after they go it alone in taking risks and gathering intellectual resources and then learn about all the people are who want to put on the brakes. It appears there is need for more communication about support for dealing with issues before the faculty member faces the 5% limit or is forced to give up grants.

Professor Bearinger said she believed this discussion responded to the request from the Faculty Consultative Committee; she can make a report to FCC or the Committee could prepare a formal statement. Professor Anderson said the consultation process just occurred, at this meeting, and she did not believe the discussion led to enough clarity to prepare a Committee statement. Professor Bearinger said she would provide FCC an abstract of the discussion, and adjourned the meeting at 3:45.

-- Gary Engstrand

University of Minnesota