

Minutes\*

**Senate Research Committee  
Monday, October 27, 2008  
2:15 - 4:00  
238A Morrill Hall**

- Present: Dan Dahlberg (chair), Melissa Anderson, Peter Argenta, Saif Benjaafar, Jerry Cohen, Tricia Conway, James Cotter, Leslie Delserone, Genevieve Escure, Tom Hayes, Michelle Lamere, Frances Lawrenz, Jennifer Linde, Timothy Mulcahy, Mark Paller, Federico Ponce de Leon, Andrew Van de Ven, Karen Williams, Lynn Zentner
- Absent: Linda Bearinger, Arlene Carney, Robin Dittman, Bridget Helwig, Steven Ruggles, George Trachte, Jean Witson,
- Guests: Mark Bohnhorst (Office of the General Counsel); Associate Vice President Pamela Webb (Sponsored Projects Administration)

[In these minutes: (1) research funding, central decisions and grass roots; (2) collaboration with outside companies; (3) conflict-of-interest policy and the Academic Health Center]

**1. Research Funding**

Professor Dahlberg convened the meeting at 2:15 and noted that were a potpourri of items on the agenda, items that have been on the list for awhile and that needed to be taken up. The first agenda item today was phrased as follows: "Per discussion 8/8/06: How is the University to deal with the decline in research funding? Interdisciplinary research & centers; what faculty need for support to compete for grants. And centrally-allocated research funds: (1) for centrally-initiated research initiatives, how is the decision made about what areas to focus on, (2) how are specific plans approved, and (3) are there alternative processes to get things on the table through grassroots or other mechanisms to allow bottom-up efforts?" One topic on that list--how the University is to deal with the decline in research funding—has changed because since it was first listed, in August, 2006, research funding has increased. And the Provost has maintained that all research initiatives are based on grass-roots activities. Vice President Mulcahy will address most of the issues, Professor Dahlberg said, and thereupon turned to Dr. Mulcahy.

Vice President Mulcahy agreed that the question of "grass roots" deserves discussion. He said he envisions two different ways that research initiatives are started. One, he might be approached by a group of faculty about an initiative or project that they are seeking support for; this is probably what most people would see as grass-roots-initiated initiatives. Two, the central administration launches a major initiative. Many faculty see the latter as top-down and not as good. Dr. Mulcahy said he would agree in general, but many central initiatives are informed by the faculty. For example, informatics could be seen as a University-level initiative, but it was selected because they kept hearing from the grass roots that informatics is important if the University is to be competitive. His office pulled the information together and made the case to the senior vice presidents. This was an instance of "the top" working on behalf of the grass roots to make something happen. He said he could not claim that that is the way these kinds of

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initiatives happen across the University, but it is the way they happen through his office. They do not decide independently to launch some initiative, and when initiatives are proposed, they frequently bring them to this Committee. Some projects do have the fingerprints of the central administration on them but they are all informed by the faculty. What is needed is faculty awareness; given the complexity of the institution and the diverse resources available, no administrator can be aware of all the opportunities.

So how do the faculty get an idea advanced, Professor Dahlberg asked? For a large number, the easiest way is to work at the college level, Dr. Mulcahy said. His office also has a good relationship with the research associate deans, so if a faculty representative for a project wants to make a case for funding, the research associate deans will discuss it—and usually projects require some local funding. He also has a research advisory group, a group of top faculty with whom he meets often to identify areas where he should seek support, such as the arts and humanities. He also receives emails directly from faculty asking for support, which he usually directs to the programs of interest because he is not in a position to unilaterally fund very much.

Many academic ideas live or die in the compact process, Vice President Mulcahy observed, because many units have more ideas than they can champion. Sometimes cross-college plans do not reach the level of priority that they get into the compact discussion, and as a result the administration is thinking about an interdisciplinary compact. The senior vice presidents awarded funds to his office and the Graduate School to support interdisciplinary initiatives. They solicit ideas from faculty that are reviewed by a faculty advisory group and some of which are funded; those funds often provide a springboard to larger funding opportunities.

Professor Van de Ven asked if there is grumbling or concern about the process, and what the context for the issue is. In 2006, Professor Cohen reported, data from the NIH indicated that of the top 100 research institutions, only three saw a decline in funding—and Minnesota was one of them. Dr. Mulcahy said he assumed the question for the Committee was about the funding priorities for strategic-positioning initiatives.

Professor Hays said that in the current NIH climate, the potential for a decline in funding is a reasonable question for the Committee to address. Medical School Dean Powell has announced that there are no longer bridge funds available PIs between grants. That is a critical need, Dr. Mulcahy responded. His office is trying to compile a list of critical research infrastructure needs, and bridge funding is one of them. The University has not set priorities for critical research needs (at the institutional level), and this could be one of them; they are trying to identify the most important ones and are listening to the grass roots to do so. The situation will probably get worse before it gets better, so the question is whether the University invests its limited funds in "the next big thing" or in the research infrastructure.

Professor Hays said that a number of faculty are affected by the situation; is there a need for a channel for faculty concerns? Dr. Mulcahy said there is not because he was providing an example of how the grass roots can affect decisions. It is the grass roots channels that raised the level of bridge funding to a critical issue. To manage a problem that large requires more coordination than perhaps the University is used to, but responding will not be as effective if the AHC or the Medical School or IT have to do so alone. It is better to look at all the resources and how the administration can help close the gap. They must look across the University, which is why they are trying to get an institutional review of research infrastructure needs.

Professor Anderson inquired, with respect to coordination, what role the Clinical and Translational Science Awards (CTSA) would play, and what if the University does not obtain one of them? The NIH is using the CTSA program to concentrate resources for clinical research in approximately 60 research institutions in the U.S. So far, 38 institutions have been awarded CTSA grants. The CTSA is expensive, Dr. Mulcahy said, but it constitutes the invitation to the ball for future funding so is something the institution must have and is working hard to get. How at risk is the University without it, Professor Anderson asked? It is speculative to say, Dr. Mulcahy replied, but in terms of reputation and funding there is a lot at risk. A lot of work in the AHC is predicated on a strong performance there, something that would be difficult to do without CTSA. Dr. Paller agreed. CTSA gets about \$500,000 in new money for the University, but it prevents the University from losing about \$5 million with grants expiring. To do this right requires a lot of institutional funds, several million dollars per year (much of which the University is already spending, but it will take a couple more million to do it right—but the University would spend the money anyway to be competitive in clinical research for infrastructure).

Professor Dahlberg said that a lot of faculty are asking questions about new institutes; many felt that they were given to the faculty from the top down. That is ironic, Dr. Mulcahy said, because all the ideas came from the task-force process, which was intended to be grass roots. Professor Van de Ven asked if there is a policy on the process. Can institutes be both bottom up and top down? The issue is transparency, Professor Dahlberg said. There is no "policy," Dr. Mulcahy said, but there are procedures to guide the process. A call for transparency raises hackles because it implies someone is intending to deceive; there is a problem in communicating opportunities. They are trying to sort that out with their initiatives; Dr. Mulcahy said he did not know if that was true across the University.

There was a problem with the initiatives, Professor Cohen said, because they were seen as central-administration driven and there was no information on how they were vetted. Informatics is very different because it is seen as a joint effort. Others seem to have sprung up. More often than not, Dr. Mulcahy said, the problem comes down to communication. In the governance system, a number of decisions have been changed because of feedback. There is opportunity for discussion in the governance system and that seems to work well.

Is there a process to review initiatives once they have been launched, Professor Argenta asked? The intent is to look at project success or failure before committing long-term funding, Dr. Mulcahy said. It has been common practice to provide funds and then never look at an activity again. To get bridge funding, they may look at initiatives and institutes that may no longer be as productive or as high a priority. Especially in this budget situation, Professor Dahlberg commented.

## **2. Collaboration with Outside Companies**

Another question to the Committee, put on the agenda by the Faculty Consultative Committee, is a standard system for negotiations with outside companies, Professor Dahlberg said. The University is viewed as tough to deal with.

Vice President Mulcahy said that issue was one of the first things he was asked to address when he took this position. The problem is that companies are sponsoring research elsewhere, not at the University. He asked CEOs about the matter and they gave him two answers: one, nine times out of ten the University is on the list when they identify places that could help them with research, and two, nine

times out of ten the University is not on the list when places that are easy to work with are identified. He has worked to address that problem. Companies see the University as virtually impossible to penetrate, as opaque; they confront "phone-tree bingo," and give up after five calls to go some place they can work with. So his office has created the Academic and Corporate Relations Center so that companies can make a single call, ask a question, and get an answer within 24-48 hours.

Companies also ask how they can keep up with what is going on at the University, Dr. Mulcahy related. They have hired academic relations managers who work with a limited number of companies and contact them about what is happening at the University that could be of interest to them. They also ask if there is something the University can do in their area of business. It has become almost too successful, because governments (U.S. and foreign) and other groups are making use of the service.

Another problem has been the length of time it takes to close a deal, Dr. Mulcahy told the Committee. At the University, it has taken months or years, so companies go elsewhere (this is a national problem, not unique to Minnesota). He has worked with people in house to look at the terms and conditions associated with intellectual property and now companies are approaching the University and like to work with it. The University will also now sign master agreements so that individual projects need not be negotiated.

The University has always had a good policy for allowing faculty to consult with industry; the conflict-of-interest policy both allows and encourages such consultation. The University is acutely aware of potential conflicts of interest but believes that if they are disclosed, they can be managed.

The University is doing a lot better in negotiating with companies, Dr. Mulcahy concluded, and the general attitude is better than it was four years ago.

Professor Dahlberg recalled that Associate Vice President Webb had talked about a flat indirect-cost rate; is that still in the works? It is, Dr. Mulcahy said, and the University is participating in the federal University-Industry Demonstration Partnership (UIDP). Universities and business must cooperate if the U.S. is to keep its lead in scientific and technical research. There are about 80 universities participating and they identify best practices. His top priority is to figure out how the University can do better at partnering with companies interested in sponsoring research at the University. Ms. Lamere reported she had been involved in setting up an internship program for postdoctoral fellows, which had been a very exasperating experience. Dr. Mulcahy said that the UIDP is setting priorities about issues that get in the way of cooperation, and they include intellectual property issues, access and awareness, and faculty-student exchanges. If they do things right, there can be more faculty in industry labs, more interns, and more company people in University labs. Ms. Lamere said one problem was a lack of clear process and consistent information from the OVPR and SPA. It took six months from her first contact with the OVPR until the internship was finalized with a Memorandum of Understanding that was felt to be heavy-handed on the part of the University. Dr. Mulcahy said he would like to know what issues were involved so that they can be addressed.

One area of pushback in working with business and industry is the potential undue influence of business and industry and limits on participation, Dr. Mulcahy said. The University has established policies and procedures it will not broach, such as free dissemination of research and participation in the work. The University will not accept funds that require withholding the results of research except for a short period of time to allow a company to patent a product. It is possible to let business and industry

influence how the academy is run—but not at the University of Minnesota. And this Committee weighs in on behalf of faculty if the administration were to bring forward something that might compromise the University's principles.

### **3. Conflict-of-Interest Policy and the Academic Health Center**

Professor Dahlberg next reported that Senior Vice President Cerra had suggested that there needed to be clarification of the Openness-in-Research policy, but the more that he and Dr. Cerra discussed Dr. Cerra's concern, it became clear it was about conflict of interest, not openness in research. He turned to Mr. Bohnhorst, from the General Counsel's office, to elaborate.

Mr. Bohnhorst noted that the Medical School is considering a much more restrictive conflict-of-interest policy. Dr. Cerra raised questions last spring about outside consulting and suggested that whatever faculty do as an outside consultant should not conflict with the Regents' Openness in Research policy. The policy provides that it does not apply to outside consulting, Professor Dahlberg pointed out. Mr. Bohnhorst agreed and said Dr. Cerra had clarified that his concern is consistency in the outside consulting policies, not the Openness in Research policy.

Mr. Bohnhorst said he had consulted with one of his colleagues in the General Counsel's office and learned that NIH is about to publish a rule on outside consulting, which could address the questions that have been raised. NIH has been criticized for not monitoring compliance with NIH policy, so the new policy might address the question of NIH monitoring. However, some observers believe the new NIH policy will address lowering the bar on when the conflict-of-interest policy is triggered, from \$10,000 to \$0. If NIH policies come forward that differ from University policy, then the University will need to consider changing its policy. Professor Dahlberg said he assumed that any proposed policy change would come to this Committee for consultation and then be brought to the Faculty Senate.

Professor Van de Ven noted a recent newspaper article saying that the University agrees that physicians should not receive any money from pharmaceutical companies. Would that apply in this case? Mr. Bohnhorst said the article concerned the proposed new Medical School policy he had mentioned. Is that is what is at hand here, Professor Van de Ven asked? The draft policy deals with both disclosure (everything) and what is permissible (fair market value of the compensation or consultation fees, which must still be disclosed), Dr. Paller said. Professor Dahlberg recalled an article in *The New York Times* a few months ago about a doctor who received a great deal of money from pharmaceutical companies. There have been several examples, Dr. Paller said, of people serving as consultants for pharmaceutical companies and doing research that affected the company's products. The same thing has happened with medical-device companies. The practice has been that some physicians elsewhere have received consulting fees and then use the company's products in his or her medical practice. This also gets mixed up in continuing education because companies provide funding for many very valuable sessions that professional societies do not have the money to support.

Professor Cohen said that he had a consultantship with a large company that led to research funding for his lab, and he decided not to take consultantship money because he was worried about possible personal gain. He said he believes the University must have a clean slate in this area and it is worth investigating. The quandaries that arise can put even people who understand the rules in an indefensible position, especially with respect to human health issues, when there is an interlocking of

personal and research dollars. One wonders if the rule should be that if one receives research funding from a company, one should not be allowed to be a consultant for that company.

Dr. Paller said that one of Dr. Cerra's questions is how something that the Academic Health Center sees as essential will affect the rest of the University. Is it acceptable for the AHC to have one standard and the rest of the University another, or should there be one institutional standard? The Committee and the attorneys can both help advise whether a single policy is possible. Dr. Mulcahy said they knew the Medical School would review its rules and have emphasized that they must be harmonized with institutional policy. If there are two systems people can get confused. He said he did not know the answer to the questions but it will be important how the recommendations are vetted and then harmonized with University policy. He noted that universities often have more sensitive policies when it comes to the use of human subjects in research.

Will there be a major recommendation on disclosure, Professor Argenta inquired? More than that, there will be prohibitions, Dr. Paller said. He emphasized, however, that the policy is in the discussion phase. One recommendation is that the Medical School take no money from the private sector for continuing education, which would be a big change and would require that money be provided from some other source. The draft also calls for NO gifts. In terms of consulting, some is legitimate and part of the land-grant mission and some is less legitimate (e.g., when the consultant is paid more than the fair market value for his or her work), but it will be important not to throw out the baby with the bathwater.

The fundamental question Dr. Cerra raised, Vice President Mulcahy said, is about the process. That must be dealt with before emotions begin to run high. There is a need to identify how to answer questions. What role does this Committee have, Professor Dahlberg asked? It has representatives from the AHC on it, Dr. Mulcahy noted, and it needs to be discussed whether there should be a single University rule. And it can play more than a vetting role, Dr. Paller added, because it can look at what the Medical School proposal might hold for everyone else in the University. What has been in the news is a straw man. The policies are fine if one is working with inanimate objects that do not harm people.

The overarching question is the integrity of the research, Ms. Zentner said. The issues should be looked at from a University-wide perspective. It may be that it will ultimately be appropriate to apply different approaches to different colleges and units. University of Minnesota Physicians (UMP) has also developed a policy, she reported, and efforts are being coordinated to ensure that UMP's policy does not impose a different set of standards on the faculty than the standards ultimately set for faculty at the University. Ms Zentner reported that she recently met with Dean Powell (the Medical School) and understands that Dean Powell recognizes the need for a review of this matter outside of the Medical School, but she also wants to bring closure to the Medical School's process.

Will there be local or school determination on these issues, Professor Van de Ven asked? It could be that the social sciences or clinical research the demand will be in relationships open to conflicts of interest that must be dealt with while engaged in close patient/student/client relationships. He expressed doubt about the appropriateness of a universal policy, given the varieties of research that take place. Dr. Mulcahy agreed and said there should be common principles applied in each research setting.

Dr. Mulcahy suggested that the Committee have a discussion with Dean Powell once the draft policy has been vetted through the Medical School. A question arose about whether UMP would have a different standard from the University. The Medical School standards would not apply to UMP, but Dr.

Paller said the UMP standard would likely be the same as the Medical School's. UMP is a subsidiary of the University, he noted, and the doctors who belong to it are University faculty in the practice plan who deal with Medicare and providers. It is a not-for-profit organization under the University's control. Professor Dahlberg opined that there should only be one policy. Dr. Paller said UMP is a separate corporation, audited by the inspector general, but in most cases it can have the same policy. The document that the Committee will see, however, is for the Medical School only, and has not been presented to all six AHC deans. It will be, he added, but has not reached that point yet.

Professor Anderson said that much of this is driven by more than Senator Grassley's investigations. Research has shown that even small incentives can influence attitudes. Other studies have shown that when researchers disclose conflicts of interest, people assume the research can be trusted, even though that very disclosure can hide bias. This goes beyond disclosure, Professor Argenta said, and could prohibit industry funding of research. One way to address faculty relationships with industry is the use of fair market value as the standard for setting the amount of compensation to be paid, Ms. Zentner said. There are ways to do that, Dr. Paller agreed, and it is done with federal grants in terms of a reasonable percentage of effort and salary. The point is that someone should not receive a lot of money for trivial work.

Professor Dahlberg thanked everyone and adjourned the meeting at 3:40.

-- Gary Engstrand

University of Minnesota