

Minutes*

**Senate Research Committee
Monday, November 7, 2005
1:15 - 3:00
238A Morrill Hall**

- Present: Steven Ruggles (chair), Mark Ascerno, Dianne Bartels, Richard Bianco, Kathy Bowlin, James Cotter, Christopher Cramer, Dan Dahlberg, Sharon Danes, Genevieve Escure, Steven Gantt, Jacob Granholm, Paul Johnson, James Luby, Brian Reilly, Thomas Schumacher, Maria Sera, Virginia Seybold, Charles Spetland, Barbara VanDrasek, Jean Witson
- Absent: Arlene Carney, Robin Dittman, Penny Edgell, Timothy Mulcahy, Mark Paller, George Trachte, Michael Volna
- Guests: Mark Bohnhorst (Office of the General Counsel); Ed Wink (Sponsored Projects Administration); Lisa Carlson (Office of the Vice President for Research); Professor Frances Lawrenz (Co-chair, Task Force on Collaborative Research)

[In these minutes: (1) report from the compliance office; (2) update on task force on research infrastructure; (3) update on task force on collaborative research]

1. Report from the Compliance Office

Professor Ruggles convened the meeting at 1:15 and turned to Mr. Schumacher to present a report on the activities of the Office of Compliance, of which he serves as Director. Mr. Schumacher said he would provide a "big picture" report on research compliance: what is happening nationally, what other schools are facing, what he hears from federal agencies, and what is happening at the University of Minnesota. He distributed a handout consisting of a number of PowerPoint slides.

Mr. Schumacher noted a "map" he had prepared earlier that indicated the risk (low to high) and the impact (high to low) of problems in the top 25 compliance areas of the University (e.g., Housing, Athletics, Fiscal, Equal Opportunity, Boynton, Immigration, etc.). The majority of the areas on the map are research-related, he noted. Many parts of the community do not recognize how complex research is for faculty and for the administration (e.g., the number of administrative units that have some responsibility for research matters, such as Sponsored Financial Reporting, privacy, property, hazardous waste, and so on).

Mr. Schumacher highlighted four "hot topics" nationally.

-- Conflict of interest: the most acute areas of concern are human subjects research and clinical trials, especially the disclosure to research subjects of relationships with research sponsors, and research drug trials and relationships (such as consulting relationships between MDs and drug companies, even though the relationship has nothing to do with the research at hand). Congress is upset about these

* 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.

relationships. Mr. Schumacher said he was worried about litigation on the national scene on conflict-of-issue matters. Another conflict of interest issue is institutional conflict of interest (such as institutional receipt of a royalty income stream from something plus researchers working in the field who might produce findings that could materially impact the flow of revenue). The AMA and the AAU have developed recommendations on how institutions should handle these potential conflicts. Another conflict of interest area of concern is that between PI and subcontractors (when the PI has a potential conflict with the company doing some of the business for the research, for example selling goods in which the PI has an interest).

-- Privacy and data security: there is a new Minnesota law (also true in some other states) requiring that any time an organization loses private data, or believes its systems containing private data have been hacked into, the institution must review the data to see if the individuals must be notified. For example, all employee data, with a few exceptions such as name and salary, are private data under Minnesota law. If anyone knows of breaches of security of private data at the University, they should send a message to abuse@umn.edu. If it involves an IRB study, they should notify the IRB.

What about research data that has nothing to do with individual people, Professor Seybold asked? It depends whether the data fit into one of the categories of the law, Mr. Schumacher said. If it is data about a patient or student, it is almost certainly private unless de-identified. The issue is VERY complicated. The key message from him, he said, is that if one believes private data have been lost or compromised, send a message and let that office deal with it. The key, Professor Danes said, is whether or not people have been de-identified. Mr. Schumacher agreed; that is one exception to HIPPA. But HIPPA is not the only rule that governs, he cautioned. What about employee information that is public by law, Professor Ruggles asked? Name, salary, directory information is public, Mr. Schumacher said. Moreover, private information can be shared internally with people who have a reasonable need to know it. The concern is about outsiders or those without a need to know seeing private data. So one should report if student research papers are stolen, Professor Escure asked? (Yes.) People should also report any loss of human subjects research data to the IRB, Mr. Bianco said.

Professor Dahlberg said that this has now been explained to the members of this Committee, but all faculty need to have the information. How is it getting out? There is under development a web-based training program required by HIPAA for everyone in the Academic Health Center, Mr. Schumacher said, and it will be offered to other faculty and researchers as well. Given that the law is involved, and ignorance is no excuse, Professor Dahlberg said, if someone steals grades with names, he needs to know that should be reported. Mr. Schumacher agreed. He suggested the Committee invite Tracy Smith, in the General Counsel's office, to discuss how the protocols work. This is a big issue and his only intent was to alert the Committee to it. At last count, there were 45 proposals pending in Congress dealing with privacy/identify theft.

-- Time and effort reporting: there are two components to this item. One is the systems and internal controls the institution has in place, the checks and balances. On this measure the University is well-positioned. The other is the substantive accuracy of the reports; an institution can build a great system but it must also be sure the input reflects the work. This issue is high on the list for regulators (for example, if a researcher claims to be putting 100% time on a grant, they will look to see if the person has other grants, teaches classes, or serves on committees). And effort certification must be based on personal knowledge (one cannot certify the effort of 240 people).

-- Cost transfers: this is a big issue because some transfers are not documented correctly. Regulators don't care just about whether the cost transfers were substantively justified; they also care that the procedures were followed; the reports must be accurate and timely. They will likely disallow costs on a review, even if substantively appropriate, because they were not documented correctly or not timely. They will also look, in audits, at cost shifts to grants at the end of a project cycle or shifts between two federal projects when one is in deficit and one is not.

-- Export controls: This is still a hot issue and the problem is that it is regulated by the Department of Commerce, which is not especially concerned about universities. Perhaps up to 95% of the material of concern is for companies. But it is politically hard for universities to argue they should be treated differently because they do collaborative research and need scholars. The severe rules expose individuals to liability. If there is any question about export-controlled materials, researchers should take the educational materials available and should talk to Mr. Bohnhorst in the Office of the General Counsel.

-- Other issues include direct charging indirect costs, untimely reporting, and funding-related stem cell research issues.

Mr. Schumacher then explained that NSF and NIH identify "hot topics" for the year in their work plans, which the University looks at in order to avoid problems. What NSF has on its list includes the quality of institutional control systems, time and effort reporting. NIH is generally doing less University-specific review because of helping with oversight over Hurricane Katrina funding and has not issued its 2006 work plan, which would identify the topics of importance.

There are also some "sleeper" issues, Mr. Schumacher told the Committee. One is the relationship between physicians and the investment industry. One study suggested that 10% of MDs have a consulting relationship with the investment industry (that is, get time to talk about cancer treatments, for example). The question has to do with insider information. There was a big New York Times article about these relationships that generated questions. Another sleeper issue is in time and effort reporting: using time charged to a grant to write grant applications or engage in other activities such as teaching. Another issue, more of a risk to the individual than the University, is whether consulting arrangements between faculty and industry are fair to the faculty member (e.g., any discovery belongs to the company; at the University, the faculty member would receive 1/3 of the income if the work is done through the University). The question is whether there is critical review of contracts faculty sign with companies.

Mr. Schumacher then reviewed some of the national news related to research compliance.

-- For example, the Chair of the House Energy and Commerce Committee expressed irritation at universities and wants information on payments/stipends to graduate students and on clinical research.

-- Universities lead the nation in privacy/security breaches. 50% of such losses have occurred at universities, which is not surprising inasmuch as they are distributed, decentralized, and favor openness in research. One can expect regulation in this area.

The University's compliance highlights are several. It has strong internal controls demonstrated across the grants management systems and is recognized nationally in this respect. The conflict-of-interest reporting systems are very efficient, among the best in the country. The University is ahead of the curve on adopting an institutional conflict of interest policy; the standard set by the University is one that

other institutions must match. The University's IRB has been accredited, one of the few in the country. Its "responsible conduct of research" has also received national attention and the University is considered one of perhaps two schools with model programs. Perhaps most important, although a lagging indicator, is that, there have been no major breakdowns, Mr. Schumacher observed.

In terms of recent University compliance actions, Mr. Schumacher also provided to Committee members copies of "Guide to Research Compliance," a small volume recently prepared. Vice President Mulcahy used this to highlight at all the things the University tells researchers they must do, and is looking at streamlining the processes. The book was prepared as a result of conversations with various research-related groups. They heard, loud and clear, that faculty should not have to shop around to get answers to questions and that compliance needs to be thought about from a faculty perspective: what do faculty need to know, and at what point in the process? The challenge is that this means getting people to know who they should talk to. This book is intended to help.

Mr. Schumacher said there is a better version of the guide on line; he asked Committee members what they thought about it. He said that they are *acutely* interested in faculty researchers' responses to the Guide to Research Compliance and want to know if this (small) integrated approach is heading in the right direction to simplify and facilitate compliance, and whether they should invest more energy to enhancing the website. If faculty have the opportunity, they are asked to please complete the on-line survey, send him an e-mail, or give Mr. Schumacher a call at 6-7852. The on-line survey is at http://www.research.umn.edu/complianceguide/evaluation_form.cfm ; the Guide is at <http://www.research.umn.edu/complianceguide/> .

They also asked the staff who answer the telephones and provide advice what they expect from people who call. Beyond etiquette, they want more training on getting people to the right place expeditiously.

The biggest compliance challenge may be resources, Mr. Schumacher said. The University needs to be concerned about this because what is coming from both regulators and stakeholders is a demand for more accountability. Funding for compliance has been flat, but the University must do more and more in compliance—with no funds to pay for it. For an individual researcher, it is hard to say that he or she should spend time reconciling accounts rather than doing research, but then compliance flows to a less expensive employee and can become pro forma. There is also a discontinuity between regulators and the academy: people look at efforts in different ways. Lawyers bill in six-minute increments; faculty say they worked on a project over the last year. There can be a failure to understand how research is done and there may be a need to change norms. Mr. Bianco added that they are getting farther behind: there is more work but no more time. Based on comparisons with its peers, Mr. Schumacher said, the University is doing well. The imposition of the Sarbanes-Oxley accounting requirements on the private sector (and those may be extended to the non-profit sector in the future) has meant an increased demand for accountants, so they can make more downtown than they can at the University. This creates a need to assure we keep our talented financial managers.

Professor Danes asked if the Guide would be distributed around the University. Mr. Schumacher said that every PI would receive one and it would be available to others as needed. It is also available on the web, as noted.

Professor Ruggles thanked Mr. Schumacher for his report.

2. Update on the Task Force on Research Infrastructure

Professor Cramer next provided the Committee an update on the strategic positioning task force on Infrastructure Supporting Scholarly Activity. They are in an aggressively consultative phase now, he said, and the plan is that task force members will meet with a number of groups across the University (IT, CLA, the clinical sciences, the basic sciences, St. Paul, Duluth, etc.). Each meeting will be with about 15 people who will be asked about infrastructure, once it has been defined. They will ask people how the University is doing, what other schools are doing, what is essential to their discipline and for them, what central infrastructure elements work well and which do not. After those discussions, the task force will assemble a more cogent report and consult with various groups (deans, faculty governance, etc.).

The definition of infrastructure they have adopted is this: the facilities (e.g., laboratories, studios, clinics) and services (e.g., libraries, computing services, grants management systems, research safety and subject protection organizations, secretarial services) needed to produce novel and influential scholarly output (e.g., publications, exhibits, performances).

Questions:

In your College's fields, where is the University of Minnesota particularly strong and what are the areas that should be targeted for growth? Why?

How do other leading schools nurture the development of these areas?

With regard to the University of Minnesota, which infrastructure components are the most essential for your College's scholarly activities in general and your activities in particular?

Of these essential infrastructure components, which work well?

Of these essential infrastructure components, which work poorly and how would you improve them?

This task force, Professor Cramer noted, has a longer timeline than some of the others; its report is not due until May.

Professor Johnson commented that "research infrastructure" seems so field-specific; the task force intends to answer for the whole University? It does, Professor Cramer said. There will be priorities, such as the criticality of parts of the research infrastructure to a number of units across the institution. One could say that that has implications for giving priority to certain fields within the University, Professor Johnson suggested—in the background, there is a valuing of certain areas of work. Professor Cramer said he did not see that as the charge to the task force; they intend to identify areas that would benefit from improvements or strong areas that should be maintained. It will be an administrative decision to set priorities and make choices. They will provide a map of the infrastructure and how the University competes with other institutions, strengths that set the University apart, and identify areas that are ripe for something new.

Are the interviews only to be with faculty, Professor Bartels asked? Initially, Professor Cramer said. They will also want to meet with scientists and Internal Service Organization directors to obtain information as well.

Professor Ruggles thanked Professor Cramer for his report.

3. Task Force on Collaborative Research

Professor Ruggles now welcomed Professor Frances Lawrenz to the meeting; Professor Lawrenz serves as co-chair of the Task Force on Collaborative Research.

Professor Lawrenz began by reporting that the task force has conducted a SWOT analysis, which follows. The SW are focused on internal factors, the OT on external.

SWOT Analysis

Strengths

- Wide range of recognized disciplinary expertise
- A corresponding general research and scholarship infrastructure
- Several special or one-of-a-kind facilities (*identifying all of them*)
- Experience with interdisciplinary research and large scale successful projects (*developing a list*)
- Existing examples of internal and external collaborations
- Strong interest of University to create a culture of interdisciplinary research and scholarship
- In some circumstances, organizational structure facilitates collaboration
- Interest and willingness of many individual faculty members to work together
- There are *some* monetary resources to support interdisciplinary collaborations (*Data [are] needed to assess whether the amount is sufficient to be considered a strength*)

Weaknesses

- Promotion and tenure follow collegiate lines and the process does not adequately credit extra-disciplinary (interdisciplinary) work
- Financial models (e.g., indirect cost return - ICR) is not conducive to interdisciplinary work
- Lack of resources, infrastructure, and space to support new large scale collaborative projects
- In some instances, the collegiate structure hinders intercollegiate sharing of resources for both financial and cultural reasons
- Principal Investigator-as-empire mentality hinders collaboration when it is present
- Center directors are often more skilled in grant getting than in leadership and administrative skill
- Our accomplishments are not highly visible, either within or outside the University

Opportunities

- Can have a larger impact on science and knowledge through collaborative research
- Emphasis by many funding agencies and foundations on interdisciplinary research (NSF, NIH, USDA, DHS, but not all)
- Other universities are thinking along the same lines and there are opportunities to establish collaborative regional and national networks (Goal would be establishing the University of Minnesota as a hub)
- Opportunity to develop and, therefore, dominate a new field

Threats

- Competing institutions are developing new mechanisms and devoting substantial resources to support interdisciplinary research and have long had interdisciplinary institutional structures (e.g., the Institute for Social Research at Michigan), and are way ahead of us
- Less and less money available
- Some national ranking systems do not adequately value interdisciplinary work

The draft vision statement reads as follows: "We envision a University that will be known internationally for its innovation and excellence in interdisciplinary research and scholarship and for the ease with which collaborations are established. This substantive and culturally supportive environment will attract highly talented investigators and team leaders from all over the world."

Professor Danes asked if the definition of collaborative research included faculty working with other institutions and organizations, as well as across disciplines within the University. Professor Lawrenz said the definition will be as broad as possible: within the discipline, across colleges, across universities. It could include units that do not include faculty, she said, but in response to Professor Danes's question about whether it could include the users of research, she said they had not thought about that possibility. Professor Danes asked that they do so, since NSF has begun to spend more time on the impact of research on users; that could be a direction a number of funding agencies move. It is important that the University be on the cutting edge.

Professor Ruggles (a member of the task force) said it is his sense the task force is concerned primarily with current barriers to collaborative research and what the University can do to foster more such research. Professor Lawrenz agreed.

Will the task force try to identify areas in which the University has potential strength in collaborative groups, Professor Sera asked? They will identify such areas and obtain information, Professor Lawrenz said, but she said she did not know if they will develop recommendations. Professor Sera said there is a need for someone to look across the University to identify potential strengths. Professor Ruggles said the task force will probably focus more on things that can be done at the institutional level rather than on particular fields.

For the social sciences, collaboration can include neighborhood groups, Dr. VanDrasek said, and that issue needs to be on the screen in an era of public engagement. They will talk about it, Professor Ruggles promised.

Professor Cramer suggested that one possible weakness was in promotion and tenure, where the strength of a paper is divided by the number of authors. Will the task force forward its assessment to the task force on faculty culture, Vice President Mulcahy asked? The issue should be addressed there and they may not know about it. Professor Lawrenz said it would be; they are using electronic communication to send materials to task force chairs and want contributions early and often.

Does the idea of co-PIs fit in the task force charge, Professor Danes asked? It does, Professor Lawrenz said. They are not specifically addressing that question but they are looking at ICR transfers. If the NIH lists more than one PI, how do units get credit? This is a barrier if one is better off with one's own grant. This is also an issue when it comes to determining why someone is a PI and why someone

else is not, Professor Danes said. There are problems that could be avoided if more than one person could be a PI; this is not just about credit or money.

Professor Ruggles thanked Professor Lawrenz for her report and adjourned the meeting at 2:35.

-- Gary Engstrand

University of Minnesota