

Minutes*

**Senate Research Committee
Monday, May 8, 2000
1:30 – 3:00
Room 238 Morrill Hall**

Present: Leonard Kuhi (chair), Daniel Brewer, Bianca Conti-Fine, Jerry Flattum, Mark Paller, Richard Poppele, Barbara VanDrasek

Regrets: John Finnegan, Lorraine Francis, Eric Klinger

Absent: Victor Bloomfield, Robin Dittman, Patricia Gladchild, Phillip Larsen, Scott McConnell

Guests: Win Ann Schumi, Ed Wink (Sponsored Program Administration)

[In these minutes: Roles and Responsibilities document; proposed University compliance plan; use of animal and human subjects in research and the desirability of peer review for research; partnerships with business and industry]

Professor Kuhi convened the meeting at 1:35 and noted that there were a number of issues left over from previous meetings that required continued discussion. These included use of animal and human subjects in research, the Roles and Responsibilities document and partnerships with business and industry. A new item has been added, the proposed University compliance plan. He turned first to the Roles and Responsibilities document.

1. Roles and Responsibilities Document

At the last meeting Committee members had been assigned the task of reviewing the revised Roles and Responsibilities document, Professor Kuhi reminded his colleagues. The document lays out what each office and individual needs to do with respect to research grants. Are there any comments, he asked?

One Committee member inquired if there are specific items that are open to question; Ms. Schumi said the question is whether the roles and responsibilities make sense for the PI, the department head, etc. Some sections of the document are not completed, Mr. Wink noted.

This is a dynamic document, Professor Hamilton said; if people have specific comments on it they should go to the "mail to" link and indicate their concern. Any comments received will go to the appropriate group for review.

There will also be language added about graduate students and post-doc employees.

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

2. Proposed Compliance Plan for the University

Professor Hamilton next distributed two documents and reported that for the last eight or nine months a group called the First Tuesday Oversight Group (consisting of him, Ms. Schumi, University Auditor Gail Klatt, Mark Fahnhorst from the General Counsel's office, Senior Vice President Cerra, and Vice President Maziar) have talked about the need to put in place a University research compliance model.

Professor Hamilton called the attention of Committee members to a structural picture of how offices interact through a compliance officer, who would receive feedback from across the University and who would be housed in the Office of the Vice President for Research. The compliance officer would report to an Academic Vice Presidents group (composed of the Executive Vice President, the Senior Vice President for the Health Sciences, the Vice President for Research, the Vice President for Agriculture, sometimes the General Counsel, and the President); the President, if he wished, would serve as chair. This group would report periodically to the Board of Regents.

This structure is typical of compliance structures found in business and in academic health centers (where it is required by law). The University is trying to establish an institution-wide structure before required to do so by law; it would (later) naturally expand into general activities (e.g., the athletic compliance office would report to the compliance officer). At present, however, the proposal is only for a research compliance officer.

Professor Hamilton asked that Committee members review the structure and read the draft proposal for the compliance program and come prepared to discuss it at the next meeting of the Committee. He explained that there are issues that have yet to be addressed satisfactorily; one concern on the part of the General Counsel's office is attorney-client privilege, which is needed to protect the innocent in the event of federal intervention by, for example, the Department of Justice or the Inspector General from Health and Human Services. (Those offices are focused on the University right now and take their cues from the metropolitan newspapers.)

Professor Hamilton also provided copies of the web page from the American Association of Medical Schools Research Compliance Resources. Compliance, he noted, is a very big and very contentious issue.

Where should the compliance officer proposal go next, he asked? To the Faculty Consultative Committee, but also to the Senate? He asked for advice. He said that he and Ms. Schumi have insisted that the document go through the governance system; faculty must be aware of it and accept it or the proposal will not fly.

Are there specific areas that Professor Hamilton wished the Committee to focus on, Professor Kuhl asked? The document seems very clear: there will be an academic vice presidents group, that people will follow guidelines and policies in sponsored project management, that if they do not follow them that information can be used to inform an investigation, that all who do research must have training, that it is the responsibility of supervisors to be sure employees are knowledgeable about policies and procedures, that knowledge of those policies and procedures is a condition of employment and failure to observe them can be a cause for disciplinary action, and so on. This puts policies into practice.

Professor Kuhi said that if faculty endorsement is wanted, the proposal should go to the Senate. While the proposal embraces actions the University must take, the Senate has approved all of them and this proposal simply formalizes a structure to implement those actions.

Comments from Committee members were to be sent to Mr. Wink.

3. Use of Subjects in Research

Professor Kuhi noted that there has been activity recently on the part of politicians to speed up Health and Human Services enforcement of compliance with rules for use of human subjects in research. Professor Conti-Fine raised questions about how the University deals with projects that use human or animal subjects but which have not been peer-reviewed by a major agency. Should there be a review panel set up to look at such projects? There are two issues involved: research protocol concerning the use of subjects and scientific validity. The discussion at the Committee has concluded that the Internal Review Board consideration of research protocol does not assess scientific validity (nor should it); the IRB only decides if it objects to the project on grounds of non-compliance with federal rules and regulations concerning research subjects.

How big an issue is this, asked one Committee member? Professor Hamilton reported that the database on the use of subjects in research is being converted and is not quite at the point where data can be provided--although it will be shortly. Ms. Keane heads the Research Subjects Protection Program; it was agreed that Professors Kuhi and Hamilton will contact her about obtaining data for the Committee.

One Committee member said that the problem needs to be addressed. One hopes there are very few cases of non-peer-reviewed projects that use animal or human subjects but there will be some. Consent, in the case of humans, has nothing to do with scientific validity, it was said. There are projects supported by drug companies, for example, that are probably valid for commercial purposes but that do not have scientific validity. There is also the issue of teaching: there are classes in biology, anatomy, surgery, and so on that use animals instead of computer-generated virtual reality (the latter of which can provide more useful information than killing an animal, it was argued). Whatever is learned from an animal treated with curare could have been learned in another way.

At least two other Committee members dissented sharply from this statement and described it as opinion, not fact. The point, came the response, is not that animals should not be used in teaching, only that the use should be examined in order to see what works. Animals are used every day and that must continue. But if animals are abused, all who use them suffer, even if one uses clean procedures. The question at hand is the use of animals or humans in non-peer-reviewed research, said another Committee member; teaching is a different matter that should be dealt with separately. Then it should be taken up in the near future, it was rejoined; the University needs to "clean up its act."

The University has been "cleaning up its act" for a long time, asserted another Committee member. The Institutional Animal Care and Use Committee takes the issue seriously. All courses that use animals are evaluated. Whether the use of animals are effective in teaching is a more complex issue that also gets into academic freedom: how one teaches is a matter of professional judgment. This is not to say the use of animals in teaching should not be reviewed but the subject is complicated.

For the time being, however, the Committee's exploration should be restricted to research because there are projects that use animals and humans that do not go through peer review. There is an ad hoc process that is used, said another Committee member, because faculty are asked to sit on panels for this exact type of situation. This process needs to be looked at and data obtained, it was said.

This is a very difficult issue about which to put a framework, one Committee member pointed out. There are perhaps 5000 protocols for the use of human subjects in research that are in place now, many without peer review. Many may not require peer review (e.g., surveys or work that is part of a course). How will it be determined if a project has been peer-reviewed, asked another Committee member? The fact that it is sponsored does not mean it has been through peer review. The University knows there has been peer review in the case of big federal projects but not in many others. There is nothing in the information maintained by Sponsored Projects Administration that indicates if a project has gone through peer review, Mr. Wink reported. This information is built into the database maintained by Ms. Keane and will be in the Electronic Grants Management System database, Professor Hamilton told the Committee.

It is surprising that information on peer review is not known, commented one Committee member. Peer review is a very formal process, Mr. Wink observed; there are a lot of informal projects that may use animals or humans. The protocols for using the subjects are reviewed, Ms. Schumi added, but not whether or not a project has been subject to peer review.

It is possible to sort out the projects that have had peer review (such all those sponsored by federal agencies or major foundations, is it not, asked one Committee member? It is. Those are no problem; if they have been peer-reviewed, they have been determined to be scientifically sound. The projects that need review are those sponsored by small foundations, private companies, or departments. Mr. Wink noted that Sponsored Projects Administration would not know about internally-funded projects, although Ms. Keane would have records on them.

NIH is focused on this issue, said one Committee member, and has charged the University to build the information into its database. Clinical trials are also peer-reviewed and the PI has not voice in the approval. Anything with FDA approval has gone through peer review, pointed out another Committee member. It is department research that is a concern; the proposal goes to the Internal Review Board for protocol review but there is no assessment of scientific merit.

Are simulations reviewed? Not if they do not use human or animal subjects, it was said. The problem is that one does not know all the variables and students can only learn by experience in many cases. Cardiovascular instruction, for example, is all by simulation, but there are problems with it. One journal publishes 37,000 pages per year; how does one pick out what to put in a simulation?

One Committee member inquired if animal welfare statutes are enforced (very vigorously). All animal holding facilities are subject to frequent internal review by the Institutional Animal Care and Use Committee. There is also a national accrediting group that certifies the facilities based on yearly and independent inspections. A facility can be put on probation by this group, which means that it cannot hold or use animals.

4. Partnerships with Business and Industry

Professor Kuhi now turned to the issue of partnerships with business and industry. In one institution, highlighted in "The Kept University," a company provided a substantial amount of money to a department for research; the question has been raised whether the department "sold its soul" to the company. Similar issues have arisen at other places. At the same time, there are partnerships that are beneficial to both the University and the company, or more to the University than the company; it is useful to have a discussion about them.

One of the Committee members distributed an outline of the issues related to such partnerships; Professor Kuhi asked Mr. Flattum to review his outline for the Committee. Mr. Flattum said that he had looked at Vice President Maziar's white paper on technology transfer, which is the term she used for strategic partnerships with the private sector. North Carolina State has a research park in which 60 companies rent space, which cost \$250 million to construct, and which has about \$10 million in venture capital to support research incubators. Vice President Maziar did not use the term "incubator" but the white paper seems to be calling for that kind of enterprise for the University. The North Carolina State facility is attracting top researchers and is essentially a small city with golf, K-12 schools, and shops.

He included the arguments against the partnerships, and their dangers, in his outline, Mr. Flattum related. When the market shifts or there is a recession, companies quickly pull their research funds. He said, however, that he believed the counter-arguments are weak and that these developments will be self-sufficient once they are started--and they will grow exponentially.

A big issue is the question of who ultimately directs University research, said one Committee member; is it individual faculty members seeking the truth or companies saying what directions research will go to enhance potential profits? The idea of academic freedom to do research "goes out the window" when companies are directing research. That has been the case for some time, responded another Committee member, if one follows the activities of NIH study committees.

One advantage is that universities retain the patents, it was said, so benefit as well. Besides, faculty will not sacrifice their ethics because they are supported by private companies. (Several faculty members on the Committee simultaneously reflected that that statement was too generous.) One Committee member recalled a statement that Dr. Bloomfield had made at an earlier meeting: there is a profound difference in what drives a company versus what drives a federal agency or non-profit foundation. Yes, researchers follow NIH, "but NIH is us": peer review through NIH is by faculty members.

Much critical has been said of NIH, one Committee member commented, but it is a "pretty darn good system" and it supports science that may not have immediate applications that can make money. The same is true of NSF and other agencies. One is not so concerned about academic freedom and good science in the case of federal agencies; privately-supported research is often for profit, some of which is good for humanity and some of which is not.

How science is directed is a tough question that need not be dealt with in connection with partnerships, said one Committee member. The issue is openness, which is missing in research sponsored by proprietary interests.

Another Committee member said there is a world of difference between saying the market should drive research and saying someone should pay the bills. One gets very nervous when one says it should be market driven. Is there only one model? The model could be different in science, technology, and the liberal arts. There is great cause for concern when one speaks about privatizing research in the liberal arts; what would be the market-driven research in the humanities? There are significant liberal arts projects in the private sector but they are not market-driven. Another Committee member agreed and said that in engineering, for example, it would be unthinkable not to have connections with industry. In some parts of CLA, however, the gulf between business and the academy is quite wide.

One can look at this kind of activity less as driven by the private sector than as using the private sector for the University's own good and its good. Harvard has an incubator allowing things to be done jointly between Harvard and the business sector that seems legitimate; the research must be conducted in those labs. There are people in some companies that actively encourage collaboration with University scientists, which the University could do so profitably for both it and the company if it had a mechanism to do so. The research would not be market-driven until something was discovered.

The key is University control, said one Committee member. Another agreed that cross-fertilization between the academy and the private sector can be profitable for both as long as it is kept in check and the academic part has the same say as the for-profit sector.

One's pet peeve is the arts and how poorly supported they are. With additional private sector support, for example, the School of Music could have a state-of-the-art recording studio and students could record works. There are such partnerships already, it was said, and considerable thought has been given to how to tap into community resources in the arts.

One Committee member suggested inviting Vice President Maziar to talk about these issues at the next meeting of the Committee.

One issue that must be kept in the mix, said one Committee member, is the University's responsibility to be publicly accountable.

One of the most successful partnerships between the University and the private sector has been the Center for Interfacial Engineering, which had major interaction with businesses around the world. It is a model that other disciplines should think about; the Committee may wish to speak with Professor Fennell Evans about it.

Professor Kuhi thanked everyone and adjourned the meeting at 3:00.

-- Gary Engstrand