

Minutes*

**Senate Research Committee
Monday, April 17, 2000
1:30 – 3:00
Room 238 Morrill Hall**

Present: Leonard Kuhi (chair), Victor Bloomfield, Bianca Conti-Fine, John Finnegan, Jerry Flattum, Lorraine Francis, Patricia Gladchild, Eric Klinger, Scott McConnell, Mark Paller, Barbara VanDrasek

Regrets: Daniel Brewer, Richard Poppele

Absent: Robin Dittman, Phillip Larsen

Guests: Moira Keane (Use of Human Subjects Institutional Review Board); Ed Wink (Sponsored Projects Administration); Professor David Hamilton (Grants Management)

[In these minutes: Use of human/animal subjects and peer review of studies; whether the University should require identification of sources of research support; department purchase orders; revised Roles and Responsibilities document (sponsored research); partnerships with business and industry]

1. Use of Human Subjects/Animal Care

Professor Kuhi convened the meeting at 1:35 and began by noting that copies of the report on the use of human subjects in research from the Office of the Inspector General of the Department of Health and Human Services were available. He asked Ms. Keane to give the Committee a brief overview of the report.

Ms. Keane said that in June, 1998, the Office of the Inspector General prepared a report about Institutional Review Boards (hereinafter IRBs) for the use of human subjects in research; the report was highly critical of the system and suggested it needed an overhaul. There were a lot of concerns about sanctions as a result of the original report. She said she had not seen this report, but it is typical for the OIG to revisit its reports to learn of progress.

Major questions in the report were whether federal policy was on the mark in protecting human subjects and whether institutions were in fact protecting them. The report found that many institutions were falling far short of compliance with federal regulations. The University, Ms. Keane said, has benchmarks so that it is sure it follows the regulations.

One Committee member observed that the University is regarded as having one of the best IRBs in the country; how does it keep track of decisions and the reasons why they were made? Ms. Keane said they try diligently to control consistency across IRB panels; there are monthly meetings with the panel

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chairs and vice chairs. There is a data base that contains all the studies; there is no data base that can track consistency of decisions.

Another Committee member expressed a concern about research that uses human or animal subjects without an adequate protocol. A PI may use either humans or animals when (1) the project protocol is sound and (2) the project is scientifically valid or meritorious. When protocols from agencies with good peer review systems are used, both criteria are met. But there is a block of research funds that are not subject to a peer review system--or subject only to a very loose system of peer review. It may be that the second criterion is not met by research funds allocated this way, and some research has been funded that may not be scientifically meritorious. Even the best IRB panels cannot review scientific merit across the spectrum; they are not expected to do so. This may happen a fair amount: a project is approved by the IRB but is not subject to peer review for scientific merit.

When one talks about peer review, responded one Committee member, one is usually talking about a PI who is seeking a grant from an agency. The IRB grants permission to use animal or human subjects in research because safeguards are provided. To require a scientific merit review before the subjects are used would infringe academic freedom. Committees could overrule good projects--and have done so. There is an important element of academic freedom to protect.

When it is a grant application, said another, the agency conducts the peer review and then decides whether to provide funding. The grant then goes through the IRB protocol. This is a straightforward process. Some research projects, however, from department funds or elsewhere, do not go through that peer review process so how does one evaluate their scientific merit? The IRB does not do so.

It is not supposed to, it was said. The IRB is instructed to assess the tradeoff between the risk to the subjects and the benefit to society from the outcome of the research. There is an implicit judgment in that decision but it is not normal peer review to assess scientific merit.

Take the example of testing cosmetics on rabbit eyes, said one Committee member. There is a safety issue, of interest to the FDA, but it would be hard to understand the scientific merit of such tests. That is a class of experiments to test products for commercial purposes. (There are no such tests conducted at the University of Minnesota, Ms. Keane interjected.) Clinical trials sometimes have that cast to them, however. Peer review panels ask if a proposal is an interesting scientific question worth investigating.

Ms. Keane pointed out that IRB approval is really a statement of no objection to the protections built into the research. It does not APPROVE research. Many institutions pre-screen applications to agencies to determine if they are worthy of the institution; the University of Minnesota does not.

A call for a review of scientific merit and adequate protocols for the use of animal or human subjects is not an infringement of academic freedom, asserted one Committee member. It is to ensure that funds, and pain and suffering, are not squandered on projects that do not merit them. The case of cosmetics is an extreme one; others require expert review. The answer to the problem, it was said, might be to use some kind of external review for projects that are not peer-reviewed to at least give a look at scientific merit.

There is not likely a large number of such projects. If one includes student research projects, the number could be large, Ms. Keane pointed out; they must be included, said another, and that means undergraduates as well. There are a lot of small projects which students may fund themselves. There are also department funds and UROP funds. Ms. Keane said there would probably be over 1000 projects that have no visible means of support, out of a total of approximately 7000 projects that involve the use of animals or humans. Most of the research on humans takes place in the behavioral sciences.

There could be a threshold, it was suggested: surveys and studies with no risk of harm to humans or no pain and suffering for animals would not require external review.

One Committee member said it would be helpful to see evidence that there is a problem that the institution can deal with. The internal review for scientific merit is not that impressive and it is unclear that it does a great deal to protect either scientific merit or research subjects. There should be reluctance to add another committee. Ms. Keane said she could provide the Committee with information.

This has serious implications, protested one Committee member. The University says it trusts faculty to teach classes from freshmen to graduate students but does not trust them to design studies in their area of specialization. With respect to pain and suffering, there is also informed consent. If the IRB has no objection, why should there be another level of review? One part of the OIG report, it was said, makes the point that no one has evaluated the impact of IRBs; that should be part of the process. This Committee passed a resolution approved by the Senate asking for a cost-benefit review of procedures at the University. It is easier to pass resolutions about cost-benefit analyses than it is to carry them out, responded another Committee member.

An evaluation of the impact of the proposed external review must be carried out, one Committee member insisted. The minute people are charged with the responsibility of review, their judgments of each other and by their peers are put to the test and they will feel pressured to find every fault to justify the existence of the committee. The committee would be charged to find fault and would create trouble where there is none.

This Committee is not at the point of recommending such a process, cautioned another. If that were true, added another Committee member, the entire peer review system would collapse. In the case of informed consent, moreover, the patient relies on the premise that what the researcher will do will be sensible but will have no clue about the scientific merit of the process. And if faculty were all competent to develop proposals, none of them would be rejected.

If data are collected, will it be possible to identify instances when human or animal research subjects were harmed because of inadequate peer review? One Committee member opined that even with informed consent people may not be fully rational and could agree to subject themselves to harm even if there is scientific merit to the project. Ms. Keane said that it is difficult to measure because one is trying to measure what did not happen. Animals do suffer some pain and distress in some experiments but there are controls in place. Ill effects befall people in research all the time, but again there are controls in place. There has been no catastrophic results at Minnesota, she said, although that statement is not true about all institutions.

One Committee member expressed sympathy for the concern about research that is not peer-reviewed but also expressed concern that it is a "tricky" matter. If the University only permitted peer-

reviewed studies, by definition almost all non-federal projects are preliminary studies that are not peer-reviewed and would thus not be allowed.

Another Committee member offered a different point. The IRB is not the primary issue. The University is at the point, after the NIH sanctions, that it needs to rationalize (a la Weber) the Use of Human Subjects system. There has been a level of informality to the process before, with guidelines. But research is a big business; how can the University be sure it is being consistent? If controls are to be tightened, the University should know WHY it is doing so as a result of a thoughtful process. There must be IRBs in place and they need the resources to carry out the process; the University must not nickel-and-dime them to death or it will get in trouble.

Graduate students must convince faculty members that their research has merit. Graduate student time constraints can be severe (as can those of undergraduates, observed another) and the impact of any proposal on them should be considered.

The Committee needs the data, iterated another Committee member. It is to be hoped that the number of projects that do not go through peer review is small, but it is a group with the potential to cause trouble.

Professor Kuhi said the discussion would be left at that point for this meeting. He asked Committee members to review the report from the Inspector General and said the topic would be brought up again at the next meeting [next fall].

2. Identification of Sources of Research Support

Professor Kuhi next turned to Dr. Bloomfield, who had raised as a question whether University policy should require listing of all sources of research support on publications. Professor Kuhi commented that he thought people did that as a matter of course.

They do so because NIH and NSF expect it, Dr. Bloomfield said. The question arises, as informal discussion right now, if one supposes there is an industry grant for a research project; should there be an expectation of disclosure as there is with research grants from NSF?

One Committee member exclaimed "I don't see why not!" Some do not require it, or want it. It should be disclosed, it was said. Some companies do not want to be identified, Dr. Bloomfield said; a flag goes up if they are listed. Sometimes support is hidden; is that a good thing?

One Committee member said that all sources of funds should be listed in research studies. Dr. Bloomfield said he was inclined to agree. If one has a consulting relationship with a firm, or owns part of the firm, University policy requires disclosure. Policy does not say that funding sources must be disclosed.

What are the funding implications if the University had such a policy, asked one member of the Committee? There are companies that would withhold funding, Dr. Bloomfield said. The usual requirement of a funding sponsor is that they must be given credit, Mr. Wink reported. Some companies do not want credit. There are legitimate reasons for companies not to be identified, said one Committee

member; in one case, in one case, the company did not want competitors to know it was interested in a general subject area.

One way around a prohibition, suggested one Committee member, would be to include a generic description of support by a company with an interest in the research. The general nature of support has been disclosed.

Another Committee member expressed surprise that there are contracts and grants where the grantor prohibits disclosure. Many journals require disclosure, it was said, to avoid trouble. It is part of the ethical conduct of research to disclose sources of funding. The public should know.

How large a problem is this? Dr. Bloomfield said he did not know. In debates about genetic modification of organisms, sponsorship by either a company or an environmental group raises antenna. It is understandable why a company would wish to hide a commercial strategy--he said he had not thought about that problem--but when research deals with a potentially controversial issue, when funding sources are revealed potential biases are also revealed.

There are two ways that secrecy in research show up in projects funded by industry. One is a prohibition on disclosing that the project exists. The University does none of this kind of research. The second is a publications clause, giving the sponsor the right to review (but not APPROVE) publications. If there is intellectual property involved, the sponsor is to be provided a chance to protect it. There has been silence on the issue of giving credit; mostly the concern has been about publication.

One Committee member maintained that there should always be disclosure. But whose responsibility is it to ensure that this occurs? The University's? Journals'? Who? There is a need for a system-wide practice, Dr. Bloomfield agreed. Universities, agencies, and journals are all part of the system. Until there is a uniform standard, however, it makes sense that there is an understanding that if something is submitted for publication all sources will be disclosed.

This should go in the code of conduct, Professor Hamilton observed.

Dr. Bloomfield thanked the Committee for providing him a sense of its views.

3. Department Small Purchase Order

Professor Hamilton said he wished to raise one small matter before moving to the next agenda item; he said he was trying to get the feelings of various groups.

The department small purchase order has a \$2000 limit if there is to be no bid. Purchasing wishes to raise this limit to \$10,000. There are many positive aspects to the proposal, but the one drawback is that departments will be at risk for \$10,000, rather than \$2,000. He said that he personally favored the proposal.

The "risk," he said in response to a question, is that a department makes a purchase that is later disallowed on a grant; the department is then responsible for the amount. Professor Hamilton also explained that a department can (as at present) obtain bids for less than the limit if it wishes.

This is a transfer to local responsibility, said one Committee member, akin to giving car keys to the kids. The University has started down the road to transferring responsibility and this makes sense, even though it feels scary.

The consensus of the Committee was that raising the limit was a good idea.

4. Revised "Roles and Responsibilities" Document

Professor Kuhi now called on Professor Hamilton to discuss the revised Roles and Responsibilities document.

Professor Hamilton recalled that the Committee had reviewed the original document in 1998 and that it has been an official University document since that time. A number of things have occurred since the document was adopted. There is new language and deleted language in the revision; he urged Committee members to read and review it. There is not, he said, anything that requires particular attention; he asked that it be read for consistency.

Professor Kuhi said the document would be brought up for discussion at the next meeting.

5. Implications of Forming Strategic Partnerships with Business and Government

Professor Kuhi turned next to Mr. Flattum, who had asked that this item be on the agenda.

Mr. Flattum said he asked that this subject be discussed in light of the article "The Kept University" that had been circulated to the Committee. He said he favored partnerships with business and that the arguments made in the article were weak (e.g., that any partnership will jeopardize academic freedom and objective scientific research). This does not seem to be an argument that holds up, he said, considering what other universities are doing. He pointed to the Carlson School of Management as a case where a partnership led to a new building. As the networked economy grows, he maintained, it will be crucial for universities to pursue partnerships, especially for funding research.

He said he also favored partnerships because they would reduce the need for the University to be beggars for state and federal grants and because they put control in University hands. The royalties can be large, he added. He expressed concern that the University is not embarked on a full-fledged program to increase partnerships with industry.

One Committee member observed that the President has proposed a forum on economic development in the state and this topic might be part of those discussions. He was, he said, not as sanguine as Mr. Flattum because he believed that "he who pays the piper calls the tune" held true for research. He noted that as a result of the University's difficulties with NIH it has established controls on the system in order to obtain and provide benefits to society while avoiding conflicts of interest.

Mr. Flattum added one other point: that if the University did not establish partnerships with industry, industry would go elsewhere. One comparable example is the growth of the virtual university in the networked economy, which could completely alter the way the University does business.

Dr. Bloomfield reflected that the value of a university to society is its trustworthiness and objective focus on the search for truth--rather than playing to one interest before another. Industry sponsorship of research need not clash with this value but the University's reputation is crucial and it must do everything necessary to protect it. "The Kept University" article damaged the reputations of research universities; the issues can be overblown but it is something to which the universities must pay attention.

Industry also values universities because of their objectivity, Dr. Bloomfield observed; if industry wants tailored outcomes it can go elsewhere. If universities lose that objectivity they are in trouble. They must have strong connections to the economy but there must also be mechanisms to ensure disclosure and conflict-of-interest mechanisms are very healthy.

In the case of one university, one Committee member observed, there was a sense that an entire department had been bought. It is easier to envision these kinds of relationships in a school of management than it is in some other instances, such as bioengineering.

Another danger, said Dr. Bloomfield, is that as universities need more and more money for research, they will go where the money is and ignore those parts of the institution where companies do not make money available.

One wonders how much of the long-term decline in state funding has been filled in with private dollars, said one Committee member. If the states do not feel that academic health centers, for example, are focusing on issues they think important, part of the solution is to provide funding to address those issues. One could ask, in Minnesota, what vital questions are not being asked by the AHC; no one has produced a good list. Part of the job of the institution, added another Committee member, is to formulate the questions.

One Committee member said he agreed with Dr. Bloomfield that the University's portfolio needs to be comprehensive; it cannot forget its broader mandate and must consider the quality of life in the state. It does seem purer to say that the University will not invest more effort to obtain more external funding from companies and will put more effort into the societal consequences of what it does. The University does not only contribute to the production of widgets but also to the quality of life.

Wisconsin has a research park outside town that is set up to keep faculty, one Committee member pointed out; it serves as an incubator from which to spin off faculty ideas. The argument is that faculty members make about 25% less than they would in the private sector and this is a way to offset that difference. The park provides square footage and connection with venture capital as a spur to keep faculty. Madison is different from the Twin Cities but this could be something the economic development conference could take up. By offering this benefit, Wisconsin keeps the activities within the university system and it is all monitored and in the open. Wisconsin also receives about \$10 million per year in unrestricted funds from the venture that it can put back into the institution--it is not charity.

Minnesota is different because of the metropolitan area, said one Committee member. Many companies in the Twin Cities can trace their origins back to the University. Three years ago there were 17 start-up companies that came from the University; the University had an equity interest in some of them. There are a lot of pitfalls and problems with a research park; the question is what the formula for Minnesota is. The question, it was said in response, remains how the University can aid faculty in these kinds of activities; many view it as part of their job.

Vice President Maziar has views on this subject, it was said, and Sponsored Projects Administration is trying to make the relationships with business and industry a little easier and facilitate deals. They want to improve that ability, Mr. Wink said, but certainly do not want to become a "kept university."

What areas of research might industry be involved in that would not be compatible with the University's objectivity? Environmental justice, for one, said one Committee member. Companies that pollute might not like what University research would show. Another is in the area of private gain versus public good, such as with the Human Genome project; patent law is far behind advances in biotechnology.

The difficulty comes when grantors have a strong proprietary interest in the research, suggested one Committee member. One can have all the appropriate disclosure and conflict-of-interest mechanisms in place and this issue remains. Is it possible, for instance, to have funding from competitors in the same lab? It is; the Center for Interfacial Engineering, for example, sponsors research that is of interest to the entire industry. Nor is it a problem if the second sponsor is told about the first, said another Committee member. Even in basic research, it was said, the University is not pristine; with federal research, if intellectual property is identified, the University turns quickly to private sources for additional funding. Even NIH funds, in higher education, go to the highest bidder. The University can pull back from such an arrangement if the company shelves the intellectual property, Mr. Wink noted.

This is a fundamental structure in this society, Dr. Bloomfield maintained; the way a public good gets spread is through private enterprise. This is not completely good, however; there are areas of society that need investment to help those who are not aided by private enterprise--and it is getting harder and harder to make those kinds of investments.

It was agreed that this topic merits more investment; Professor Kuhi promised it would be brought back. He then adjourned the meeting at 3:00.

-- Gary Engstrand

University of Minnesota