

Minutes*

**Senate Research Committee
D-Day (June 6), 2000
1:30 – 3:00
Room 433 Johnston Hall**

Present: David Hamilton (chair pro tem), Daniel Brewer, Bianca Conti-Fine, Jerry Flattum, Patricia Gladchild, Eric Klinger, Richard Poppele, Barbara VanDrasek

Regrets: Leonard Kuhi, Robin Dittman, John Finnegan, Lorraine Francis, Mark Paller

Absent: Victor Bloomfield, Phillip Larsen, Scott McConnell

Guests: Vice President Christine Maziar

[In these minutes: intellectual property policy--procedures (start and end of meeting); use of human/animal subjects in research and peer review protocols; compliance policy; issues for next year]

Professor Hamilton convened the meeting at 10:05 and announced that Professor Kuhi was out of town and had asked him to chair the meeting.

1. Intellectual Property Policy--Procedures

The principal reason for the meeting, Professor Hamilton said, is to take action on the procedures that have been prepared to accompany the Intellectual Property policy. When the policy was approved by the Senate, administration, and Board of Regents, it was with the understanding that it would not go into effect until procedures were prepared and approved by the President and the Senate. The procedures were not completed until after the last Senate meeting of the 1999-2000 year had taken place but the Faculty Consultative Committee has the authority to act on behalf of the Faculty Senate between meetings; the procedures, if approved by this Committee, will go to FCC on June 12 for interim adoption.

Professor Hamilton apologized for the rush but said it was very important for the University to get the policy and the procedures in place. The discussion of the procedures will occur when Vice President Maziar joins the meeting, he said.

2. Use of Human and Animal Subjects in Research

Professor Hamilton next noted that the Committee had discussed at some length the issue of the lack of peer-review of some research projects that use animal or human subjects. Professor Klinger, he recalled, had sent a thoughtful email to the Committee following the most recent discussion; he turned to Professor Klinger (attending the meeting by teleconference) to comment.

* 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.

Professor Klinger said that his basic concern is that the existing procedures for approval of research protocols using animal or human subjects inhibits research, especially by undergraduates in courses who need quick approval for class research projects. He also has the sense, he said, that there is a flow of incentives to institutions to tighten procedures and that there is no logical stopping point to this phenomenon. All institutions are running scared because of pressure from Congress, NIH, Health and Human Services, and so on; this pressure creates the fear that faculty will lose the right to do research.

The problem is that there is no check on the extent to which human subjects have been hurt (or animals, but that is a different matter). There is no indication of how bad things were earlier compared to the present. Any time anyone discovers there was harm to some human subject in research it becomes an obsession--as if it is possible to have a world with no harm to any human subject. The result has been a ratcheting up of pressure and more bureaucratic difficulties presented to doing research.

There are degrees of concern, Professor Hamilton said. One should be VERY concerned about clinical trials not subjected to peer review using drugs; there is much less reason to be concerned about undergraduate students conducting a survey. Professor Klinger agreed but said he was concerned about the overload on the Institutional Review Board (hereinafter IRB, which must approve protocols for all research using human subjects); the approval even for exempt projects, such as student surveys, can take three to four weeks. There is a lack of quantification of the problem, it is diffuse, and it focuses on institutions and Principal Investigators strictly following procedures to avoid harm--and punishment for not jumping through more hoops than necessary to avoid harm.

There are two separate issues involved, Professor Hamilton said. One is that the Institutional Animal Care and Use Committee (IACUC) and the Institutional Review Board are concerned that there be good procedures and good treatment of animals and humans. The second is the issue of scientific validity. Redundancy cannot be avoided in teaching; the question is whether it should be in assessing scientific merit.

If protection of subjects also requires judgment of scientific merit, Professor Klinger responded, then another procedure has been added and there is also a threat to academic freedom. He affirmed he believed in the protection of human subjects but said that investigators must be free to try out ideas that are strange or incomprehensible to their peers; that is part of academic freedom. A committee judges the probability of success and could choke off highly innovative and paradigm-shattering research.

Professor Hamilton noted that Professor Klinger teaches Psychology; students must do research involving humans for theses. A group of faculty looks at the proposals to decide if they have some validity so there is peer review. He would contrast that, Professor Hamilton said, to a clinician who has access to non-sponsored funds who single-handedly develops a protocol for an investigation involving humans. The research subjects could be inadvertently harmed.

Professor Klinger again agreed but said that the line has gotten blurred. To make subjects feel bad subjects one to a lawsuit. The Institutional Review Board turns down proposals that contain any risk that there will be emotional discomfort or embarrassment to subjects.

Professor Conti-Fine said that Professor Klinger was correct to be concerned about academic freedom. To her, she said, academic freedom means the right to believe and to teach what one wants without fear the University can fire you. It preserves the basic values of society and the evolution of

thought without regard to pressures. Academic freedom does NOT give anyone the right to impose unnecessary pain or discomfort on sentient creatures. There are egregious examples in both Europe and the U.S. where this has happened (the worst example is the Nazi concentration camps). The Institutional Review Board protects against UNNECESSARY pain or discomfort; humans may impose pain on animals in order to survive, but they may not impose unnecessary pain (e.g., they may not torture them). This is not an academic freedom issue, she maintained.

Professor Klinger said he agreed, with qualifications. Academic freedom includes freedom of unfettered investigation. With respect to imposing discomfort, that is covered by proper informed consent. If there are subjects who, for any reason, with incentives, consents to a degree of risk, that should be allowable and the state should not interfere. In addition, he said, when one speaks of "necessary" the argument should be couched in terms of "desirable," because NO research is NECESSARY; all could continue to live as they do. The extent to which it is desirable to inflict discomfort at the human level is one issue; with animals the discussion is much more tangled and one gets into the nature of consciousness and rights. If, with humans, there is fully informed consent, there should be no other barrier to the research, he contended.

This is an important topic, Professor Hamilton, and could go on forever. How can the Committee come to a point where it develops something of value that has an impact on issues?

His position, Professor Klinger responded, is that investigators should be relieved of some restrictions, especially those that require a substantial loss of time. Professor Hamilton reported that Vice President Maziar is directing \$250,000 in recurring funds to the Institutional Review Board that had earlier been removed; that will speed up the process. There is also a need for a careful look at the processes, he said, in order to be sure there are not delays.

Professor Conti-Fine said she was sympathetic to a proposal to allow PIs not to waste time. Given the nature of what they do, and given what occurs in her lab she receives close IACUC and IRB review. She said she wants those offices to be as efficient as possible. She said, however, that she took exception to a proposal to lift restrictions on investigators; they are under federal scrutiny because they have not been restricted ENOUGH. As modern biology allows more and more different kinds of research, restrictions must be in place and must be present in conjunction with good procedures to review research protocols to protect patients.

Professor Hamilton said he agreed with Professor Conti-Fine but pointed out that some implementation is left to local interpretation; some federal rules obfuscate, he observed, institutions try to enforce them, and then the federal government investigates alleged violations based on the local interpretations.

It was agreed that Professors Brewer, Conti-Fine, and Klinger would meet during the summer to compare notes and try to prepare a draft statement that the Committee could consider. Professor Hamilton suggested that this topic could be part of fora offered as part of training in the responsible conduct of research.

The discussion continued. Professor Brewer said it was his sense that informed consent does not justify passing the buck of responsibility and that it is not clear one could ever inform sufficiently to justify certain kinds of interventions. Professor Hamilton agreed and said he had seen many informed

consent forms that he could not understand, so he assumes the average person could not understand them, either. What is the alternative? Informed consent can be done properly, Professor Conte-Fine said, but even if subjects understand the consent form, they will not understand whether the research is necessary. That is why peer review is needed.

3. Compliance Policy

Professor Hamilton recalled that he had provided to the Committee a proposed policy on compliance and a proposed organization of the effort. He asked if anyone saw any problems with it. Does it provide sufficient protection for academic freedom? Is the faculty protected from an over-zealous compliance officer?

Committee members said the proposal was acceptable. There remains a need to clarify how the policy applies to students, but that clarification waits on federal government decisions concerning required training. A quick estimate suggests there are 22,000 people at the University who may have to be trained. Even high school teachers brought in for two or three months in the summer have to be trained about ethics. Everyone has to learn about OSHA rules and about handling animals; this adds another element to the required training, Professor Hamilton said, and it is not clear how the University will accomplish all this. There will be a web site that people can use. An element of trust will always be part of the program; the University cannot police what people do once they sign in on the web site.

Is it possible to have three- or four-hour sessions on a Saturday morning, Professor Conte-Fine asked? Students could be required to sign in.

Professor Hamilton said he would raise these issues with the Faculty Consultative Committee on July 12.

4. Issues for Next Year

Professor Hamilton next inquired of his colleagues what issues they would like to see on the agenda of the Committee next year. He will be bringing policy drafts and the Committee will take up the Brewer--Conte-Fine--Klinger proposal. Several suggestions were made.

- Rather than simply reacting to pressure, what the Committee (University) can do to stimulate and facilitate research; what can the Committee do to enhance the research enterprise? How can the Committee become more active in seeking ways to improve the University's climate for research?
- Re-examine two issues raised by the review of the Graduate School: (1) find ways to bridge gaps in funding because laying off people in a lab for six months is a disaster, and (2) identify funding for things useful for research but which are normally hard to fund, such as symposia.
- The Committee should understand the University's financial structure because often where people think there is flexibility there is none; if people understood the structure, they could work within it. (There may be pockets of funds in departments and colleges that are used productively for research purposes, but the Committee concluded it would be impossible to identify and make use of those funds for broader institutional purposes.)

It would be useful to have such funds available rather than money spent on more new buildings, it was said.

- It might be useful to inquire what constitutes research and how research has changed as the University has changed. For example, interdisciplinary research is occurring in ways and areas that were not even dreamt of 20 years ago. That, in turn, draws into "The Kept University" issues, which will be on the agenda in the fall.

5. Intellectual Property Policy--Procedures

Professor Hamilton now welcomed Vice President Maziar to the meeting to review the proposed procedures to accompany the Intellectual Property policy approved earlier by the Senate and the Board of Regents.

Dr. Maziar recalled that the policy was developed last year through a team effort by faculty governance and the administration. When the Regents approved the policy, they asked that before it went to effect there be procedures in place to support it; they asked that these procedures be adopted by the end of June. The President will not approve the procedures without (1) a signal from faculty governance that the faculty approves them and (2) agreement from administrative units that they are workable.

She then proceeded to review the constituent parts of the procedures.

- Disclosure of Potential Intellectual Property

- Disclosure of Potential Conflict of Interest: this aligns with the University's general conflict of interest policy. A key element is that the Patents and Technology Marketing (hereinafter PTM) staff will work with the inventor to be sure the Annual Report on External Professional Activities (AREPA) form is updated and contain any new relationships the faculty might have to disclose. (The AREPA form was previously known as Form 15.) If the form is updated, it is immediately available to the department chair and the college administration for review (as the chair now does on an annual basis). If there is any conflict of interest that has to be managed, the department and college are brought in at the outset. No licensing agreements will be put in place until this review of external professional activities has taken place.

- Clarifying Definitions: defines out-of-pocket expenditures, which could include support from other University units that is "well beyond that customarily provided" to support PTM or Sponsored Projects Administration (e.g., designation of most of the time of an attorney in the General Counsel's office to one project). Such charges would NOT be made for the work of any unit in the Office of the Vice President for Research. The definitions also make it clear that intellectual property created as a part of fulfilling course requirements or theses and dissertations is covered by the policy.

- Handling Net Income Derived from "Other Intellectual Property": "other intellectual property" is that created or developed at the University but outside of normal academic and scholarly activity (e.g., software in support of PeopleSoft) that may have commercial value. Such intellectual property is not treated the same way as regular academic intellectual property because the former is the result of assigned work. There is not the same justification for one-third share of IP-generated income as there is for academic work. At the same time, there should be room to acknowledge and reward the creation of

intellectual property by University employees. The procedures provide for ways to allocate income and call for identifying all those who were involved in the development of the intellectual property.

This procedure creates a framework to ENCOURAGE the University to share the income; it is allowed to create a benefit with this policy. One Committee member pointed out that someone could quit and begin a new company; Dr. Maziar said that is why the policy and procedure creates incentives so that employees stay at the University. This procedure tells supervisors about ways to promote the good ideas that come from their staff members.

-- Waiver of University Rights or Acknowledgement of No University Rights: there are instances where the University wants to make it clear it has no continuing interest in the intellectual property rights for something. PTM may only issue a waiver after full and complete disclosure. A waiver may be issued because PTM has determined something has no commercial value or after it has tried and failed to protect and license something. PTM may also issue a waiver acknowledging that there is no University interest, as in the case of regular academic work such as books, papers, and lecture notes. By academic tradition and in accord with the new Intellectual Property policy, those work products belong to faculty members. Universities around the country are trying to claim rights to these products, especially in distance education; Dr. Maziar said she believed that was inappropriate and would discourage faculty from using technology.

Dr. Maziar said that to deal with routine requests from publishers the University will put a letter from President Yudof on the PTM web site explaining the University does not claim and never has claimed intellectual property rights in normal academic work. In the case of insistent claims from publishers, however, PTM will issue waivers.

-- Notifying Sponsors: the Principal Investigator has the responsibility to notify PTM about the creation of intellectual property. PTM, in turn, has the responsibility on behalf of the institution to notify research sponsors about the creation of intellectual property when required. This is especially important with federal grants.

-- Distribution of Equity and Revenue from Equity: the University may license intellectual property and receive equity as part of the consideration for a license. The creator of the intellectual property will receive part of the equity if not a founder of the company providing the equity. A creator will be considered a founder of the company if he or she owns 5% or more of the company; if a founder, the individual will not receive part of the equity that is given to the University in exchange for the license (because the individual is presumably receiving rewards as major owner of the company).

-- Material Transfer Agreements: governs receiving and sending materials from a source that requires a material transfer agreement.

-- Resolution of Disputes: disputes arising under the policy are to be referred to the Vice President for Research, who is to consult with the General Counsel, the Senate Research Committee, and others as appropriate. The Vice President is to report annually to the Faculty Consultative Committee on the number, nature, and resolution of such disputes. It may be that FCC will wish this report to be made to the Senate Research Committee.

-- Intellectual Property Policy Acknowledgement: this provision is a mandate of the federal government; the University must protect the federal government's interest in intellectual property created with federal support. The University must require employees to sign a document acknowledging they are aware of the policy provisions and agree to abide by them. The law applies to federally-sponsored projects; since the Intellectual Property policy applies to everyone, it has been agreed that the University will not hunt down every current employee to get them to sign the acknowledgement but it will ask all new employees to sign; the form will be a part of their file. Continuing employees will only be required to sign if they are asked to do so. This requirement will also be incorporated in training for PIs in the responsible conduct of research and will emphasize to them that if they have staff on a federally-sponsored project they are responsible for reviewing this requirement with those staff.

Visiting scholars and researchers pose a special problem; the University's Intellectual Property policy applies to them but they may also be bound to their home institution's policy--which may conflict with that of the University. The procedure asks that the employing University department provide the employee with the acknowledgement form before he or she comes to campus so that if there is a conflict, PTM can work with the home institution to resolve it.

Dr. Maziar said she was very proud of the policy and procedures because they are very supportive of faculty and what a university is about.

Professor Hamilton then pointed out that this is the time when members of this Committee should voice any concerns; the procedures will be carried to the Faculty Consultative Committee for interim action next Monday. There were no objections; it was moved, seconded, and unanimously voted to accept the procedures.

Dr. Maziar thanked the Committee. She said she knows it is also interested in discussing the issues raised in "The Kept University" article in THE ATLANTIC; it was agreed to set aside time in the fall for the discussion.

Professor Hamilton then adjourned the meeting at noon.

-- Gary Engstrand

University of Minnesota