

Minutes\*

**Senate Research Committee  
Monday, September 11, 2000  
Room 433 Johnston Hall  
1:00 - 2:30**

Present: David Hamilton (chair), Melissa Anderson, Victor Bloomfield, Daniel Brewer, Robin Dittman, Esam El-Fakahany, Eric Klinger, Leonard Kuhi, Phillip Larsen, Mark Paller, Eric Klinger, Scott McConnell, Sharon Neet, Richard Poppele, Barbara Van Drasek, Linda Zinter

Regrets: Jerry Flattum

Absent: none

Guests: Ed Wink, Winifred Schumi (Sponsored Projects Administration), Vice President Christine Maziar

Other: John Finnegan

[In these minutes: report for public distribution; discussion of "The Kept University" articles from THE ATLANTIC MONTHLY (about the possible conflicts with business/industry sponsorship of research); issues before the committee (including conflict of interest policy, use of human subjects in research, declarations required by policies, secrecy in research, use of animals in teaching, and support for post-docs.)]

**1. Introductions and Report**

Professor Hamilton convened the meeting at 1:00, welcomed everyone, and called for a round of introductions. He then turned to Vice President Maziar.

Vice President Maziar distributed copies of a brochure that was prepared for the State Fair. She had learned after many conversations, she said, that many citizens of the state have no idea where University research support comes from; there seems to be a sense that it receives large block grants that are split up by the President, Senior Vice President Cerra, Executive Vice President Bruininks, and herself. The purpose of the brochure is to explain how faculty compete for funds on a national stage and that two-thirds of the funds come from the federal government. It also highlights the role of the University as an economic asset to the state. The point is to convey the message that the University is doing a lot and is among the top universities in the country in sponsored research.

Vice President Maziar also noted that the local newspapers had written articles about the substantial increase from 1999-2000 to 2000-2001 in sponsored research funding for the University; the increases came in expenditures, awards, and proposals made and were broadly-based. Professor Kuhi

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inquired if there any particular areas that accounted for much of the increase; Dr. Maziar responded that the increase was because of "the raw brilliance and talent of our faculty and staff" and that while there was one significant increase in the Army High Performance grant, the increases were significant across all units.

## **2. Discussion of "The Kept University"**

Professor Hamilton asked Dr. Maziar to comment on the article "The Kept University," which appeared in The Atlantic Monthly earlier this year. [The articles can be found at <http://www.theatlantic.com/issues/2000/03/press.htm>] The basic thesis of the articles, Dr. Maziar said, is that universities since World War II, and especially since the 1980s, have increasingly been doing research in partnership with industrial and commercial interests. The authors are concerned about the university's ability to pursue truth dispassionately and to serve as a place that welcomes all questions. These are important concerns for all faculty, students, and administrators and it is important the institution periodically check itself.

She was less pleased, Dr. Maziar said, about the quality of the arguments; they deserved better treatment. Some facts and figures would cause a first-time reader to reach certain conclusions, but one can see that the numbers were used cleverly and perhaps not entirely truthfully. The article reports on potential conflicts of interest, for example, and leaves one to draw the conclusion that authors of studies did not report the potential conflicts, which is not true.

Professor Hamilton observed that industry support for academic departments (a focus of "The Kept University") has been going on for years and years. In one case, there was an \$80-million, 10-year grant to a small department at another university; it would be interesting to know if the faculty in the department reported the support. Clinical studies often have industry support, he also noted.

Dr. Paller agreed and said it would be helpful to have local guidance on the issue; at present there is none. There are federal regulations on disclosure and there have been recent suggestions that a faculty member should have no involvement in research where he or she has a financial conflict of interest. The latter may be too stringent. With respect to human subjects, he reported that Greg Koski is the (first) director of the Department of Health and Human Services' new Office for Human Subjects Protections (which replaces and expands the role of the former NIH Office for Protection from Research Risks). The major changes are 1) the office serves all of Health and Human Services, not just the NIH, and 2) an academic clinical researcher, not a government bureaucrat has been selected to lead human research initiatives. Dr. Koski, Dr. Paller reported, is leaning toward eliminating all financial conflicts--but he will not do it unilaterally because he is very thoughtful. But there is a need for definite guidelines, Dr. Paller said, and the University should have statements. If there is any financial conflict, the faculty member should not be the Principal Investigator. Current federal language, however, is too complicated and too vague.

Would it be helpful to have a statement from this Committee to stimulate writing a policy, Professor Hamilton inquired? Dr. Bloomfield noted that the University does have a Conflict of Interest policy that deals with these things, although it does not cover everything. For example, it requires disclosure when a company in which a faculty member has a financial interest sponsors research in that person's lab, but does not disallow such a relationship if a suitable management plan can be devised. He pointed out that Harvard and MIT have both decided they could not manage financial conflicts of interest

so have banned them; Dr. Maziar added that it would be useful to ask them why they believed they could not manage the conflicts.

Dr. Bloomfield said "The Kept University" article raises difficult issues. It is NOT a violation of conflict of interest policies, for example, if a study is sponsored by a drug company, the results are published, and the faculty member has no financial interest in the company. But such a study is often greeted suspiciously anyway. He related that he has asked in the training sessions on the Responsible Conduct of Research if such an arrangement is a conflict; most believe it is. It is not. There is no requirement that faculty report sponsors of research if they have no financial interest in it. (One would expect journals to ask about sponsorship but most do not.)

There is, Dr. Bloomfield continued, a difference between research (1) the results of which will ultimately involve human subjects and go to the FDA and (2) research in the physical sciences and engineering. There is more sensitivity to research using human subjects.

Professor McConnell said he had a different reaction to the article. His question is about academic integrity and whether it is possible to conduct a study with integrity if funds come from a private-sector source. He said he worries about controls on the results and on publication. There are also instances when work has financial implications. There are a number of fundamental issues raised; some are opportunities, some are risks, some about the "keptness" of the university, and some are about the tenor of the place. The article talked also about the effect on other universities; do they direct attention to the places that bring in the most money?

The authors failed to discern how universities subsidize some of their units at the expense of other units, Dr. Maziar observed; it failed to acknowledge that there are large subsidies across campuses. The Dean at Berkeley (one focus of the articles) argued that the research support from outside expanded the pie rather than requiring taking money from one unit and giving it to another. She said she would have to see the agreement with the company involved at Berkeley before reaching any conclusions.

Assistant Vice President El-Fakahany suggested looking at a declaration about PI status: if a faculty member has a chance to do research, but has a conflict of interest, the individual should step aside as PI. He or she could still contribute to the research but the authors of research results should declare that there was a potential conflict of interest on the part of one team member. A similar declaration should be made when teaching.

It is interesting that conflict of interest issues become more interesting to the public when they are FINANCIAL conflicts, Dr. Maziar observed. There have always been professional, ego, and other kinds of conflicts of interest.

Professor Klinger agreed and said he was struck by the extent to which he has heard about this problem in other contexts, such as the reduced likelihood that non-significant results will be published. This is not a new issue, he said, but he added that the University should not impose requirements that are too stringent unless its peer institutions do the same because it will drive away young investigators. It would make sense, he said, to organize an AAU-level policy; it will be important to have a uniform policy across institutions. Dr. Maziar said there is steam building behind such an effort, in part because of pressure from the Department of Health and Human Services on issues related to the use of human subjects. This is causing institutions to look at all research policies.

It would be a good idea to have a broader set of policies, Dr. Bloomfield agreed. He said he was impressed by the policy adopted by the Society for Gene Therapy, which provides that none of its members may have a financial interest in companies that sponsor their research. It is better to have broad "buy in" by scientific communities for such policies.

Dr. Bloomfield went on to say that there is a more general issue involved: a skepticism about any research sponsored by a corporation or non-governmental agency, a view that any such research is suspect on its face. Such support should be declared, he said, but there are mechanisms such as peer-review and openness of data that are supposed to guarantee research so that sponsorship should not matter.

In her discipline (electrical engineering), Dr. Maziar commented, one always cites the sponsor. Also in her field, industry-sponsored research is not suspect; it is seen as an opportunity to work in areas that may have immediate relevance to business and industry and to harvest tools from federally-sponsored research for use in the world. One place where industry support has created charged feelings in research is with stem cells, Professor Hamilton observed; that is because industry was the ONLY source of support, Dr. Maziar responded.

Professor McConnell said he wondered if a general erosion of peer review and the proliferation of journals means the question is not if one will get published, but where. There is a danger in prohibitions such as the one adopted by the Society for Gene Therapy, he said, because it erodes the peer-review process. One would hope that peer review could eliminate questions about research; obviously, such review should be more attentive than normal if there is a potential conflict of interest. That assumes one knows about such a conflict, Professor Kuhi observed.

Dr. Paller said he also would not want to see such a strict prohibition. It may be the case that in a scientific development there is only one person who can carry it forward to the point of use; sometimes if one removes the person who made the original discovery, the effort will die. What is wrong with the University having the same policy as journals? It would be a violation of policy if researchers do not disclose potential conflicts of interest when they submit a manuscript? The rule should be that one must always disclose but include an option not to, with appropriate approval, if there is such a need.

The disclosure should be of a financial interest, not just sponsorship, Dr. Bloomfield added.

Dr. Maziar said that "The Kept University" also missed the mark when it suggested that the Bayh-Dole act is the reason universities and industry are working together in a more unhealthy way. That argument is all wrong, she maintained. Bayh-Dole created modest incentives to protect intellectual property for work that was not previously pursued because it did not have such protection--work that might get to the public as new products or processes. The Bayh-Dole act was NOT an instrument calling on universities to make as much money as possible. Most, she said, do not, and only occasionally "hit a home run" that allows it to put money back into its research efforts.

A consequence of "The Kept University" and similar articles, and the misreading of the Bayh-Dole act, Dr. Bloomfield said, is that reputations of universities as society's main honest brokers and seekers of knowledge are tarnished in some circles. Some like controversy, and some do not like research, and as more of these ideas get around, the more confidence in universities is shaken. He said he did not know what can be done except to be sure the University's house is in order and its processes

effective. Also bothersome, Dr. Maziar said, is that large companies who make donations to the University with no strings attached are tarred as well.

Dr. El-Fakahany agreed. He said that all a university can do is toughen its rules, regulations, and policies about what happens to someone if they do not adhere to expected canons of research. But if a university gets carried away, he pointed out, almost anyone could be found to have a conflict of interest. The rules and policies must be very clear, Dr. Maziar agreed, but the whole area is a moving target so guidelines might be more appropriate than rules. It is more critical to project the value of scientific and scholarly integrity, the value of truth, and of faculty who promote such values. There are things being done in the Graduate School and elsewhere to advance the importance of ethics in the conduct of research, which is all to the good, she said.

Professor McConnell related that he has often felt, vis-à-vis the rules and guides about the ethical conduct of research, that they ask faculty to say they have done nothing wrong to the best of their knowledge. Faculty should also declare what they HAVE done: that they have no financial interest in the research, the principles they follow, and what they will do. Oversight bodies monitor to be sure people are not doing anything wrong; the positive needs emphasis as well.

The problem, Professor Poppele said, has been exacerbated by the money involved. Clinical trials are very expensive and no one runs additional trials to check results. It becomes a money game; with the stakes increased, the question of ethics becomes more difficult to deal with.

Dr. Maziar said her office relies heavily on the University's policy prohibiting secrecy in research. She tells people that the University does not accept secret research and that it is not doing anything hidden. Faculty and students are expected and encouraged to publish results. It is important that the faculty and the public know this, Dr. Paller said.

Professor Hamilton said he found this to be a valuable discussion and that he would ask a small group to develop a position paper on which the Committee could focus its attention at the October meeting. He thanked Dr. Maziar for leading the discussion.

## **2. Various Matters**

Professor Hamilton then told the Committee that he had intended to bring to the meeting the position description for the compliance officer but that it was not yet finished. He said he would distribute the compliance plan and position description for the October meeting.

Professor Hamilton distributed copies of the policy on "Charging of Direct and Facilities and Administrative (Indirect) Costs." It will be adopted before the Committee can discuss it but it can be changed if the Committee believes it should be. The policy needs to be in place for submission to NIH in order to finally remove the University from exceptional status. The policy replaces and rearranges existing policies and is intended to be easier to read.

## **3. Issues Pending**

Professor Hamilton recalled that at the June meeting of the Committee there had been discussion of the issues the Committee should take up during 2000-01. He prepared a list and asked for comments on it. He and the Committee touched briefly on several of the items on the list.

-- On the conflict of interest policy, Professor Hamilton reported that NIH continues to be critical of the University's policy because the definition of significant financial interest is too business-oriented. Those working with the policy have struggled with language; it will be brought to the Committee in November. They are waiting for a reaction from NIH on whether the revised language meets the requirements of federal law.

-- On the use of human subjects in research, there were lively discussions at Committee meetings last year, Professor Hamilton recalled; Professors Brewer, Conte-Fine, and Klinger were to bring a report. Professor Klinger said he will send a report before the next meeting that will cover the use of both animals and humans in research. Professor Hamilton said that he expected to have data from Moira Keane about the amount of research conducted without peer review; one of the questions raised last year was how to deal with the authenticity of research that was not peer-reviewed.

-- The Faculty Consultative Committee will take up the issues associated with the libraries and academic publishing, so this Committee should wait to see what comes of those discussions. Professor Brewer said he thought this issue involved the reallocation of library funds from social science to technology journals; that decision has been rescinded, Dr. Bloomfield reported. It is unclear what the role of this Committee is, Professor Hamilton observed; there is a Senate Library Committee that is active, and it is not clear how this Committee relates to it.

Professor Klinger said that he hoped, when the University bargains with journal publishers, that the coordinate campuses are covered by any agreements about on-line journals. Some agreements exclude other campuses, but the on-line journals and indices are too expensive for the smaller campuses.

-- On facilitating faculty research, it is appropriate for this Committee to deal with the subject, Professor Hamilton said. There has been a slew of earlier reports; most of their recommendations have been implemented, interestingly enough, and it is odd that the subject still requires discussion. Professor Carole Bland (for the Committee on Faculty Affairs) is heading a group looking at this issue; she and the members of her committee should be invited to meet with the Committee.

Professor Hamilton suggested to Ms. Dittman that she and Associate Vice President Pfitzenreuter pay close attention to this issue because the implication of any action is that money will be spent.

-- The policy concerning secrecy in research has attracted concern; some feel that there is a hidden agenda in the Committee's decision to review the policy. The only reason it is on the agenda is because it is an old policy that deserves another look in a more modern context.

-- With respect to the Principal Investigator Eligibility policy, there is already a clear policy in place but there are no procedures associated with it. There is the potential for abuse without procedures, Professor Hamilton said.

-- The last page of the Intellectual Property policy includes a declaration one must sign affirming that one has read the policy. The declaration has made some angry, in the discussions about the

responsible conduct of research; one person said it smacked of McCarthyism. The Committee needs to consider how to make the statement more palatable to the faculty.

-- There needs to be continued discussion about the use of animals in teaching. This is a charged subject, Professor Hamilton said, and it was not clear to him how the Committee should deal with it. There needs to be a document to focus on.

-- Dr. Bloomfield reported that he, Assistant Vice President El-Fakahany, and Professor Seybold are developing a document addressing questions of support for post-docs. It will not include graduate assistants, he said in response to a question from Ms. VanDrasek, because graduate assistants are registered in the Graduate School while post-docs are largely unrecognized in the University's administrative and support operations (e.g., with respect to email, benefits, and so on).

Are there any other issues, Professor Hamilton inquired? Professor McConnell asked that a report be provided on the training about the responsible conduct of research. Dr. Bloomfield said he would ask Professor Seybold to come to the meeting when the topic is on the agenda.

Professor Hamilton adjourned the meeting at 2:30.

-- Gary Engstrand

University of Minnesota