

Minutes*

**Senate Research Committee
Monday, November 12, 2001
1:15 - 3:00
238A Morrill Hall**

Present: Scott McConnell (chair), Gary Balas, Victor Bloomfield, James Cotter, Kris Davidson, Robin Dittman, Leonard Kuhl, Sharon Neet, James Orf, Mark Paller

Absent: Melissa Anderson (on leave), David Hamilton, Phillip Larsen, Susan Miller, Diane Nguyen, Stephanie Root, Virginia Seybold, Sarah Shoemaker

Guests: none

Other: none

[In these minutes: (1) upcoming policy reviews (secrecy in research and exemptions); (2) unit expenditures of indirect cost funds; (3) research infrastructure; (4) conflict of interest]

Professor McConnell convened the meeting at 1:20 and began by welcoming Professor James Orf from Agronomy and Plant Genetics to the Committee.

1. Review of Agenda

Professor McConnell then noted that there was originally to be a discussion about research secrecy and industrial secrecy, at the request of Vice President Maziar, but the item has been put off, probably until next month. There are two University policies involved, one dealing with contracts with private organizations that may include restrictions on releasing research results and the other concerning secrecy and exceptions to be granted by this Committee. Since the events of September 11 there has been an increase in requests for secrecy in research, so there may be a number of requests for exceptions coming to the Committee.

Civic engagement has been a controversial issue in discussions at the Faculty Consultative Committee, but FCC has asked this Committee to talk with representatives of the Task Force on Civic Engagement about the implications of civic engagement for research. Professor Fogelman, chair of the task force, will join the Committee at its next meeting.

2. College Expenditures of Indirect Cost Funds

Professor McConnell turned next to Ms. Dittman, who distributed a table of data indicating the categories in which colleges spent their indirect cost funds (ICR) in 1999-2000. She reviewed the numbers briefly with the Committee.

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An important point is that it has often been said that all money is green and that it can be spent however the units wish, Dr. Bloomfield said. He has always taken from that statement the implication that while money is transferred to the colleges as ICR funds, the colleges mix the money up with all their other funds. This table suggests that colleges keep the funds identified as ICR funds. That is correct; they do, Ms. Dittman responded, and they are encouraged to do so--they are also encouraged to spend the money on indirect costs if that is how they receive it. Accounting Services will scrutinize large transfers of ICR funds to other accounts (one exception is for debt service).

In looking at the final two columns on the table, one of which indicated total expenses charged to ICR funds (by college) and one of which indicated ICR revenue received by college, Committee members noted that virtually all units had received more than they spent. What happened with the difference, Professor McConnell asked? Either the funds were transferred to another account or they contributed to the ending balances for the year, Ms. Dittman explained; the balances can be rolled over each year.

Asked if she had noticed anything in particular in the numbers, Ms. Dittman said she had been surprised at the relatively small number of categories in which expenditures of ICR funds were made. Most units are doing the same thing: spending the funds on salaries and fringe benefits, supplies, and so on. Dr. Bloomfield speculated that the salaries might be for clerical and secretarial support--the kind of costs that ICR funds are intended to cover. Professor Kuhi expressed doubt one could draw that inference; Professor McConnell asked if Ms. Dittman could split the salary/fringe benefit expenditures into faculty, P&A, and civil service staff. Ms. Dittman said she could do so.

There is no indication on this table whether balances are growing, Professor Kuhi observed. Ms. Dittman said she would bring those data back to the Committee.

Do colleges use the ICR funds in planning and in the compacts, Professor Balas asked? They do, Ms. Dittman said. Is the income consistent with the estimates? Ms. Dittman said the colleges are asked to estimate ICR income for each budget cycle; they are getting very good at it.

In terms of all money being green, Professor McConnell commented, just because colleges spent the money in the categories identified on the table does not mean they spent it for ICR-like expenses; could not the money cover faculty, or associate deans, or an event coordinator, or anything else? Much depends on the dean, Ms. Dittman said. Many forward the money to departments (after the dean takes some of the funds); others may not. There is no way to say whether the money is used to pay a person who is doing research. On the other hand, funds spent on Sponsored Projects Administration and Sponsored Financial Reporting are closely aligned with their intended use.

Professor Orf asked Ms. Dittman if she had any concerns about the categories in which the money is being spent. She said she did not; ICR funds are considered unrestricted money (except that the University must justify the amount it receives for buildings--that must correlate with what the University spends on buildings).

Professor McConnell said he was left with the assumption that there is a logical basis for the charges (defined as research infrastructure) but it does not seem like a big jump to conclude that the funds might be going for things that should not be supported. They may be spent on things that are not research to the original basis for recovering the funds from external agencies, but this may not be auditable, Ms. Dittman agreed.

There was talk about the University providing funds for conflict-of-interest paperwork, Professor Balas said, to cover the costs of accounting, the paper trail, and so on. Is it possible to get credit for that as a valid expense? Only to the extent that people's time is included in the ICR rate, Ms. Dittman said. That is part of administrative expense, which is capped at 26%, Dr. Bloomfield said. Professor McConnell observed that the University does not have a difficult time reaching the 26% cap, and since that amount cannot be increased, it would not be worth the effort to document the time on conflict-of-interest paperwork. Would tracking faculty time be a legitimate expense, Professor Balas asked? That would be a direct expense against the grant, Ms. Dittman said.

Ms. Goldberg pointed out, apropos the foregoing, that research simply does not pay for itself; the University can document indirect costs of 51% but only receives 48%.

Professor McConnell thanked Ms. Dittman for her report.

3. Research Infrastructure Discussion

Professor McConnell next drew the attention of Committee members to a handout he had prepared as an attempt to provide an overview of how the Committee would tackle the larger question of research infrastructure support. One issue the Committee should consider, he said, is what services and equipment are needed but that cannot be funded with ICR money or that are too expensive for a PI to pay for. Understanding the research infrastructure may permit the Committee to propose policy changes to achieve the level of support it is believed is needed. There are four areas to consider:

- Indirect costs and indirect cost recovery ("follow the money"), which the Committee has already started on.
- Status of the infrastructure (informal and formal support across multiple investigators, the impact of the arrangements, the sources of funding, the oversight, the business models that may be used)
- Investigator perspective (where is the infrastructure working, where is it inadequate?)
- Areas for further consideration later in the year (indirect cost rate, central allocation of ICR funds, ICR allocation to colleges, funding for creation, operation, innovation/expansion within "infrastructure units").

Would it be worthwhile to understand the variability across colleges in terms of how they allocate ICR funds, Professor McConnell inquired? If so, he asked Committee members to identify appropriate associate deans who could be invited to join a meeting. Other Internal Service Organizations would also be worth looking at, he suggested.

Dr. Bloomfield suggested representatives from IT, CBS, CLA, and the Medical School as examples of different approaches. He urged, however, that the focus not be exclusively on ICR funds because doing so would miss part of the picture. He noted that he administers \$2.7 million in matching funds that are not tied to ICR (money provided by the central administration to the Vice President for Research); these funds support such things as the Center for the Humanities, Neurobehavioral development. Professor McConnell agreed and said that centers should be added to the list.

Professor Davidson recalled that when Professor Hamilton first brought up the idea of looking at research infrastructure, it included review of historical development. Earlier, an investigator simply put an electron microscope (for example) in a grant application--and the funding available for research allowed including it. That practice has withered. This is a local concern but it is also a national concern that needs voicing: how expensive equipment is funded. There are also probably a lot of unrecognized examples where investigators include items in grants that could be shared with others across the University. Dr. Bloomfield agreed and added that the important part is often not so much the money to buy the equipment as the staff needed to maintain and help investigators use it.

On the question of sharing equipment, Professor Kuhi observed that if three or four investigators share something, it can be charged to a grant; if more people use it, it is seen as University research that should be paid for from University funds. Rules do not now permit sharing a large piece of equipment.

Dr. Paller reported that the AHC Finance and Planning Committee has reviewed the AHC Internal Service Organizations and this Committee should receive that report. It addressed a large number of issues; each of the ISOs is unique in its funding and the way it is structured. Some are very efficient; some are not charging for all their costs (e.g., not putting an electron microscope on grants).

Professor McConnell pointed out that this larger issue is not just about equipment or accounting for funds; it is about the intellectual vitality of the University and whether PIs have access to unusual resources they may need to do their work. It is also about achieving efficiency and collaboration in a way that the University benefits. Some collaboration on equipment can pull PIs together in a way that new opportunities will be recognized that would not otherwise be seen. That is a benefit, and there is an opportunity cost if the University does not have structures that connect PIs across disciplines.

It would be helpful to have someone from the Vice President for Research office to explain how they make decisions to support certain interdisciplinary areas and not others, Professor Balas suggested. Dr. Bloomfield said he or Dr. El-Fakahany could make such a report.

Professor Orf said that large pieces of equipment wear out or technological changes require that a new piece of equipment be purchased or, with centers, something is prominent for a few years but then something new comes along and the University may not want to continue the previous center. What mechanisms are there to provide a sunset or to turn over equipment or to justify a new piece of equipment, he asked? Professor Davidson added that agencies should have separate ICR funds for major equipment and should be fully aware of equipment needs.

Major equipment proposals to NSF or NIH usually have matching requirements, Dr. Bloomfield noted. An effort to obtain large pieces of equipment need a "hero" to champion them, Professor Davidson commented. Dr. Bloomfield agreed; to talk about the institution purchasing a piece of equipment is not helpful because a "hero" is needed to keep up with equipment needs and to evangelize on its uses. Professor Kuhi suggested that what is needed is a depreciation fund for major equipment and agencies that understand it and provide money for it.

One would hope to reduce the need for "heroes," Professor Davidson said, but in at least some fields there is need for larger and larger pieces of equipment. At the same time, small working apparatus needed for continuing research is often scarce.

Professor Neet observed that the University of Minnesota, Rochester, has not been mentioned but it will be equipment-intensive and could be a case of building from the ground up. It will be interesting to see what they do as UMR plans for funding research.

A related topic is the libraries. The question is whether the University should do more centrally, Professor McConnell said. The libraries are an example of something for which central administration is responsible for managing for the good of all and the colleges are not asked to fund them. Digital technology is another example, Professor Orf said. Professor Balas remarked that there had been no money for equipment in the Digital Technology Center; it drives people crazy when there is a new building but no understanding of the cost to maintain it.

It is difficult to even contemplate how to reallocate a finite amount of funds among a nearly infinite number of worthy uses, Dr. Bloomfield said. Professor McConnell related that he had recently been reviewing grant-in-aid proposals, which are incredibly diverse and for which there is no rational basis on which to make a judgment about which will be funded except to give the proposals to experts and let the social process decide. He said he was not sure he could help decide if someone should have a particular piece of equipment but does believe he can be part of the consultative process that decides how to decide. The process, he said, is robust.

The reason for talking about infrastructure is because there may be gaps in what is provided, Professor Davidson commented; those gaps need to be identified. Perhaps a well-done poll would help.

4. Conflict of Interest

Professor McConnell turned to Dr. Paller to lead a discussion about conflict of interest and the recent proposal from the AAU on the subject.

Dr. Paller said his efforts with respect to conflict of interest started as a question about whether it would be useful to put together in one place all policies that exist for clinical research. There are a number of such policies about publications, conflict of interest, and clinical research; some are at the AHC level and some are all-University but they may not be well-disseminated. Some are embedded in the way the conflict management committee deals with questions rather than in any guidelines.

For example, in drug trials there are three phases; in the second phase one might have hundreds of subjects while in the third, which is the stage at which FDA approval is being sought, there might be thousands of subjects. There is a growing feeling (evidenced in part in the AAU statement) that the possible gain is too tempting for a PI with a financial stake in the outcome to allow him or her to analyze the data that would lead to FDA approval. Nor need the interest be financial; an approach to the data could be unconsciously affected by factors such as ego or career advancement and promotion, although the financial incentives/rewards are the biggest issue in the mind of the public. Universities must be sure they have the public trust, he said.

In general, Dr. Paller said, the view is that if one is engaged in phase 3 trials, those analyzing the data should not have a financial interest; that is the position generally taken by the conflict management committee. The AAU statement takes the position that one should not have a financial interest in ANY trials. His view is that if that position were to prevail trials would not get done.

It would be useful to provide clarity on these issues, Dr. Paller concluded, and it would help to put all of the relevant policies in one place in order to help the public know what rules the institution has. This means a more aggressive marketing of University protections in instances of conflict of interest, Professor McConnell said; Dr. Paller agreed. In addition, he said, although he believed that it is Institutional Review Board (IRB) policy, there should be a statement from the University that financial conflicts of interest are always disclosed even if the conflict is managed. The AAU statement calls for always disclosing sources of support for all publications; if that is appropriate, why should not the University make such a statement as well?

Does the AAU statement have thresholds, Ms. Goldberg asked? It waffles on them, Dr. Paller said. It suggested there should be none, Dr. Bloomfield said. It said that disclosure and management of conflict are not enough but that there should be no conflict, Professor McConnell added.

That point should be discussed, Dr. Paller said; he does not subscribe to it but some do and the University should say if it does or does not. Much of what it in the AAU statement is easy to do and the University sometimes has a more conservative approach for which it should receive credit.

Professor Davidson said the focus on financial issues demonstrates that the concern is about public perception. Is there a connection with legal issues? Should one ask a lawyer what could be attacked? If a researcher is given approval to conduct clinical trials but something goes wrong, there could be a lawsuit; could a lawyer attack the financial stake of the PI? There was a case at one university, Ms. Goldberg related, where the PI was found to have criminal liability and went to jail and the institution had to pay a lot of money. A lawyer could also attack secrecy, Professor Davidson said, so the institution is damned if it does and damned if it doesn't. That situation should not, however, guide University policy, he said.

The non-financial factors--such as ego--are more difficult to control for, Professor Balas said. Does that mean no professor should be allowed to conduct clinical trials? Professor Cotter said he saw the AAU statement as guidelines to HELP the researcher so he or she does not slip up.

Is there no record from the conflict management committee, Professor Neet asked? She noted that the Senate Judicial committee prepares abstracts of cases so people can see the precedents. The same could be done with conflict management. The Committee could make that recommendation, Professor McConnell suggested.

Dr. Bloomfield said he was involved with the Executive Vice President and Provost's Conflict Review Committee, which considers cases outside the AHC. It took about a year of experience with cases for it to get comfortable with the principles and procedures. Once it did, it was feasible and helpful to draft boilerplate language for incorporation in plans for managing potential conflicts of interest that reflected three guiding principles: the right of students to pursue their research without undue pressure from commercial interests, disclosure of private support to funding agencies, and disclosure of sources of support in publications and presentations. There is no reason this boilerplate could not be made public.

Is there a de facto national standard, Professor Davidson asked? The standard is close to what the University does, Dr. Bloomfield said, although the University is more advanced and more thoughtful about these issues than many institutions.

Much in University policies tells me what not to do, Professor McConnell said; the question Dr. Paller is raising, it seems, is how to describe University investigators' efforts to avoid tainting our work and reputation as researchers by managing potential conflict. He said he was reminded of Dr. Scheman's presentation last spring about trust: University research is trusted because there is no conflict of interest. The University should describe how it manages conflict; publishing information could help.

Professor Neet said it is ironic how intercollegiate athletics monitors itself and repeatedly gets into trouble. Professor McConnell responded that that may not be a good model for research conflict of interest.

There is also a need to think about institutional conflict of interest, Dr. Paller said; the AAU statement put off that issue. The University receives money from royalties, and while it is only a small part of institutional revenues, no one wants to see it disappear. If the University does not stay interested, no one will, which is the reason the Bayh-Dole Act was passed, which allows universities to receive money from product development and patents. Before Bayh-Dole, once research was conducted and made public, no one would pursue it because they could not patent it. There should be a way to obtain money from such a stream and put it to use.

The licensing policy includes giving money to the PI? It does, so there may be an inherent risk for conflict of interest, Professor McConnell said. One should not prevent inventor participation in early stages of research, Dr. Paller maintained, but one could prohibit participation in phase 3 work. If the inventor cannot participate in early stages of research, no one will pursue an idea and invest in it. The value of an idea must be proven in early-stage work and the "hero" must often be the person or group that came up with the idea. The conflict must be managed, however, or the University will lose its trust.

That is exactly what University forms are intended to do, Professor Balas said; they document one is working on research and has a financial interest in a separate company. He said he thought that mechanism provided a structure to disclose conflict beforehand. This information is made available to administrators and to peer review committees, Dr. Paller said, but it is not made public. Some of the information should be disclosed, he said, and journals or the IRB may require it. If it is good practice, why not endorse it?

Dr. Bloomfield noted, with respect to the AREPA form, that the dean should contact a faculty member if the conflict of interest threshold is met to work out a conflict management plan. A sponsoring agency must be informed if there is a conflict; journals should also be informed and the conflict revealed if the investigator gives a talk. The dean and the faculty work out the plan, which is sent to the conflict review committee; the plans are usually approved--with moderate tweaking--and sent back to the dean to implement. That process should be made more well-known and codified, Professor Balas suggested. The University does it now and no one knows, Dr. Paller agreed; it appears that nothing is being done. The American Association of Medical Schools is also developing a set of principles.

Dr. Bloomfield said he recognized every point in the AAU report; the University is very close to them on all points. There is, however, little at Minnesota in the way of policy on institutional conflict of interest--which is common. The added value of the AAU document is the value of a national scholarly organization taking a position rather than letting each institution reinvent the wheel. Typically, each institution develops its own policy or is told by the federal government what it will be. There is a value in

scholarly organizations establishing professional standards; this Committee could say that the AAU report is a very good one.

Professor McConnell said the Committee should have a motion for the next meeting; Dr. Paller agreed to draft one and circulate it for review. Ms. Goldberg cautioned that actions must be in concert with Regents' policies. The intent is to fill in the holes, Dr. Paller said, not create more restrictions. The goal is to make it obvious the University has a lot in place. Professor McConnell said he would also encourage the University to continue discussions with the AAU so that the leadership comes nationally, not locally.

Is there a pamphlet or booklet one could look at, Professor Davidson asked? That is a good idea, it was said. Perhaps the boilerplate language used in conflict management plans should be sent to the entire faculty, Dr. Bloomfield suggested, rather than only to the deans, as is now the practice. In analogy with the regular legal system, there are laws, and cases decided; the procedural standards derived from applying law to cases could be made known.

Professor McConnell adjourned the meeting at 3:00.

-- Gary Engstrand

University of Minnesota