

Minutes*

**Senate Research Committee
Monday, March 24, 2003
1:15 - 3:00
238A Morrill Hall**

Present: Gary Balas (chair), Victor Bloomfield, James Cotter, Dan Dahlberg, Sharon Danes, Sabine Fritz, David Hamilton, Paul Johnson, James Luby, Sharon Neet, James Orf, Virginia Seybold, Thomas Schumacher, Charles Spetland, Charles Stech, Barbara VanDrasek

Absent: Melissa Anderson, Gerry Baldridge, Kathleen Conklin, Robin Dittman, Steve Gantt, Yev Garif, Katherine Klink, Phillip Larsen, Scott McConnell, Mark Paller, Ted Powell, Mehul Vora

Guests: Edward Wink (Sponsored Projects Administration); Assistant Vice President Richard Bianco, Professor Robert Cipolle (Conflict of Interest committees); Professor Richard Brezonik, Ms. Peggy Sundermeyer (Responsible Conduct of Research); Professor Joe Konstan (Federal Demonstration Partnership)

Other: a Daily reporter

[In these minutes: (1) conflict review committees; (2) education in the responsible conduct of research; (3) the Federal Demonstration Partnership]

1. Conflict Review Committees

Professor Balas convened the meeting at 1:15 and welcomed Mr. Bianco and Professor Cipolle to talk, with Dean Bloomfield, about the Conflict Review Committees.

Dean Bloomfield began by telling the Committee that a few years ago the Board of Regents adopted a policy on conflict of interest, a policy that had been approved by the Senate. That policy created one or more conflict review committees to review potential conflicts of interest related to sponsored research in order to help guard the University and its employees when risks to their integrity and reputation would outweigh the value of the proposed research. The first conflict review committee was set up in the Academic Health Center and has been chaired since its creation by Professor Cipolle; Mr. Bianco is the administrative representative. Somewhat later, a second conflict review committee was set up for those units that report to the Executive Vice President and Provost (EVPP) (except for the faculty in the bargaining unit at Duluth). The two committees meet independently but there is cross-membership and they try to be sure they are handling cases in the same way and applying the same policies. The AHC committee, he said, has a much heavier workload than the EVPP committee.

* 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 represents the views of, nor are they binding on, the Senate or Assembly, the Administration, or the Board of Regents.

Mr. Bianco explained that the committees are involved with potential conflicts of interest in research and both report to the Vice President for Research so there is consistency and centralization of the review and application of standards. Each college in the AHC oversees its representative on the committee (except for Nursing, which has opted not to send one). The AHC committee meets quarterly; it has thus far dealt with about 150 referrals since it was created and has had 35 so far this year. As reporting improves, deans are referring cases more efficiently so the committee has gotten more business. The referrals are not all potential conflict of interest cases; some are requests for advice on how to manage potential conflict.

The primary goal of the policy and the committees is to protect research results that emanate from the University, Professor Cipolle explained. The Regents' policy deals with multiple areas: financial interests, executive interests (e.g., serving on a board of directors), professional referrals, and so on. Most of the cases come from the deans; the AHC committee reviews every case on an individual basis. The committee is very active and its members do a lot of work; they work with the faculty on the case referred and almost always go back to the faculty member for clarification. They also receive a lot of help from Patents and Technology Marketing, Sponsored Projects Administration, and the Office of the General Counsel.

Both committees have representatives from almost all the colleges they cover and also have one or two outside representatives, Dean Bloomfield said. The external representatives are required by Regents' policy to be sure the outside community understands what the University is doing and to be sure decisions "pass the sniff test." Mr. Bianco noted that the Institutional Review Board (IRB; it must approve proposals using human subjects in research) and the Institutional Animal Care and Use Committee (IACUC, which must approve research proposals using animals) also have external members. Those committees also pay careful attention to conflicts of interest and set up management plans when there is a potential conflict.

Professor Cipolle said the conflict review committees try as much as possible to avoid becoming the limiting step in doing research. The IRB will not approve a proposal until the conflict-of-interest issues have been dealt with. His committee meets once per month so it does not delay proposals. Vice President Hamilton pointed out that actual conflicts of interest are not allowed; the two committees address POTENTIAL conflicts and try to ensure that they do not become conflicts of interest.

Dean Bloomfield reported that it is standard procedure for the Executive Vice President and Provost committee to ask several questions when a faculty member proposes to do research sponsored by a company in which he or she has an interest: what will be the effect on graduate students? have they been notified of the potential conflict of interest? do they know where to turn with questions? to whom they should go if they believe research is being steered in commercial directions? This is less of an issue for the AHC committee, he said.

Faculty are also supposed to disclose an interest in research when they submit an article or make an oral presentation, Dean Bloomfield said. SPA is to disclose such an interest to others as needed (e.g., the federal government) that research may have a commercial application. This is all standard procedure. Most of the cases are from the Institute of Technology and most involve cases of faculty as consultants for big companies (with a contract value over \$10,000 per year); the company may want to sponsor research in that faculty member's lab. It is usually possible to work out the possible conflicts. When the issue involves a small company that a faculty member owns a large share of, that is more of a problem in

the AHC. In those cases, Mr. Bianco commented, something must go: either the faculty member is a researcher and the company cannot sponsor the research or the faculty member must relinquish interest in the company. In all cases, he said, there has been 100% cooperation and conflicts have been resolved.

Asked about cases, Professor Cipolle said the most common is when an individual inventor has disclosed an invention through Patents and Technology Marketing and the company wants to market the invention with the cooperation of the faculty inventor. Dean Bloomfield said the committees work closely with Patents and Technology Marketing, which makes sure that a faculty member has an updated Report of External Professional Activities (REPA) and a management plan in place for any potential conflict of interest before they will seek licensing or patents.

How is the process working and what could be improved, Professor Balas asked? Professor Cipolle said he was pleased with the relationship with the faculty who have self-disclosed potential conflicts. They have this process in place for five years and only once has he ever had a gruff conversation. They propose a management plan to the faculty member and negotiate with the individual so there are no surprises to either the committee or the dean.

Who is responsible for overseeing the management plans once there has been agreement, Professor Seybold asked? When the faculty member and the dean have agreed to a management plan, the college oversees it. But for agreements across colleges, the process is complex, Professor Cipolle said; they have created the RRRP (research-related review panel), composed of deans or their designees, to engage in long-term monitoring and quality review. They also assess if the plan has been adhered to and review its length, Mr. Bianco added. The primary responsibility for following the plan, however, rests with the faculty member, the department head, and the dean, he said.

Conflict of interest management is a hot issue for the federal government right now and the University is well-positioned to deal with it. The University's preparedness was part of its getting removed from exceptional status with the federal government, Mr. Bianco commented.

Professor Balas now noted that the REPA form is to report on past activities, while the ROC (Request for Outside Consulting) is to report new activities. How has the system worked, he asked? Why not keep all the self-reporting on the REPA? Vice President Hamilton agreed that there is confusion about the two forms and that the ROC has not worked well. He said there is a lot of work to do to bring the ROC and REPA together; this Committee will be involved, he said. The REPA is supposed to perform both the functions Professor Balas mentioned, Mr. Bianco said; if one files a ROC, and knows there could be a conflict of interest, a new REPA must also be filed. How will this be made to work, Professor Balas asked? Vice President Hamilton said they should be brought together in the same form.

It is also difficult to know to whom to send the completed forms, Professor Balas said. The forms are pre-populated with the names of the deans, Dr. Hamilton said, but there is a 30% turnover in department heads each year; they cannot keep up with that rate of change. The primary appointment should also be straightforward but it is not, Mr. Bianco added. Dr. Hamilton said the deans have dissented from the complex forms and who should file them. He said he needed a solid reason why something is wrong: the appointment data are from PeopleSoft, and if wrong there, they are also wrong for the REPAs, so many departments need to fix their appointment information.

Professor Balas thanked Mr. Bianco and Professor Cipolle for joining the meeting.

2. Responsible Conduct of Research Education

Professor Balas turned now to Professor Brezonik (chair of the Faculty Education Advisory Committee) and Ms. Sundermeyer to lead a discussion of the Responsible Conduct of Research training. Ms. Sundermeyer distributed a draft document outlining the components of a continuing education program in the responsible conduct of research. Professor Brezonik recalled that the Senate had passed a policy calling for initial and continuing education in the responsible conduct of research; the continuing education portion of the program has not yet been implemented. The draft will be modified as needed following conversations with groups such as this Committee and then will be submitted to Interim Vice President Hamilton for implementation in 2003-04.

There are two components to the program. One is informational:

"The Office of the Vice President for Research (OVPR) will maintain a Web site with current information on regulations and policies related to research conduct. The Web site will be updated as needed and will encompass a broad range of regulations, policies and guidelines. The Web site will allow faculty, PIs, and administrators to access the site at their convenience for a rapid overview of changes in regulations and policies. The site will be a starting point for links to more in-depth information.

"While faculty and other PIs will exercise discretion in reviewing those portions of the material that are relevant to their research, scholarship, and outreach, the expectation is that the materials will need to be reviewed at least annually. PIs will need to have completed the review of the material on this site within the 12 months that precede a grant/contract award (date on the Notice of Grant Award). EGMS will remind PIs of this requirement at the time of proposal submission."

The second component is awareness/discussion:

"To implement this component, the University will provide a wide variety of venues to maintain awareness and promote active discussion of RCR issues among its faculty, research and professional staff, and academic administrators. These individuals will be expected to participate periodically in "active learning" activities related to responsible research and scholarship or professional ethics. The activities may be at the University or off campus (e.g., at other universities or professional conferences). The activity might be a lecture given by someone with expertise in the topic or a structured discussion among colleagues. The expectation is that faculty, professional staff, and academic administrators will participate in this activity at least once every three years.

Many faculty activities meet this requirement, such as:

- Department seminars dealing with topics in RCR or professional ethics
- Programs sponsored or co-sponsored by OVPR, such as the University-wide Forum Series, or by other centers, such as seminars offered by the Center for Bioethics
- Seminars, lectures, programs or other sessions at professional societies, other universities, or other institutions on relevant topics
- Teaching part of one or more courses or workshops for faculty or graduate or undergraduate students on research and professional ethics

- Service on committees, such as the Institutional Review Board, the Institutional Animal Care and Use Committee, or the Conflict Review Committee

The information component would be fulfilled with an authenticated visit to the web site, which would then be captured in the PI database and be included in Responsible Conduct of Research reports. The awareness component would include links to web sites and a link to PeopleSoft so people can report what they attended and the event would be recorded. If attendance at an on-campus event is chosen to fulfill the requirement, registration for the event will be included in the database. The only time a self-report would be needed is if an individual attended an event not sponsored by the University.

Professor Balas asked if the initial training is continuing for new people at the University. Professor Brezonik said it is; if one has participated in that training, one need not do so again. Is the information changing dramatically enough that the information component of the proposal is enough to meet the objectives? Professor Brezonik said the information in the initial training is relatively timeless and he saw no need for people to repeat it. As for the continuing education, he turned to Dr. Hamilton.

What they have in mind, Dr. Hamilton said, is that they would send news to PIs about any significant changes in federal regulations, local policies, and so on. They would not rely on people going to a web site or an education session if something is so important that they need to know about it immediately. People also want more timely access to information, Professor Seybold said. Ms. Sundermeyer said they have heard from attendees at the education sessions that they want a single point of contact about issues, so the Vice President's office will have a single web site to which people can go with questions that experts can address.

There will be email reminders to faculty about the need to attend a continuing education session on a three-year cycle, Dr. Hamilton said. They will not, however, ask for reports on attendance at session; that would be impossible for them to track. They will assume honest reporting.

Why is this required, Professor Dahlberg asked? What motivates this? There are a number of motivations, Professor Brezonik replied. The program stems from a time when the University had serious problems and was put on exceptional status by NIH. Starting in 1998 the University began implementing procedures so it is more ethically conscious and so that people are trained about appropriate conduct. Now all faculty, administrators, P&A staff, graduate students, and even some undergraduate students must go through training in professional ethics.

Professor Dahlberg said his question was about the three-year cycle. It seems as if something specific led to this being required and that people will not be able to pick and choose what they need. What is this needed for? This program is part of policy adopted by the Senate; the actual format came from the Faculty Education Advisory Committee, which Professor Brezonik chairs, Ms. Sundermeyer staffs, and which includes a number of faculty as members.

They take the Senate policy as a given, Professor Brezonik said; it requires initial training and continuing education in the responsible conduct of research. The latter element has not been implemented up to now but the Faculty Education Advisory Committee does not believe it is optional. They are trying to implement the requirement as unobtrusively as possible; the issues are broad and there is more than one way to meet the requirement.

This is also an era when a lot of ethical issues confront people in the University as they do research--conflict of interest, treatment of graduate students and postdocs, research secrecy, etc. This can be viewed as part of the general educational mission of the University to help students and faculty themselves understand the issues, Dean Bloomfield said. There is no one unique path; there are different issues in different fields so the program allows for a buffet of options.

The program also reflects dual goals, Professor Seybold said: what people need to know, so the University does not get in trouble again, and ethical issues, not defined in documents, that need to be discussed and integrated in behavior.

After being informed that cross-disciplinary forums were not well attended, Professor Balas suggested there be seminar series in departments; that would be a more direct way to get people involved. Ms. Sundermeyer said they have discussed such seminars and believe it a good idea to support activities at the local level. A lot of ethical questions are discipline-specific, Professor Balas said, and with fewer funds for outside speakers, department seminars may be one way to accomplish the goal. Dr. VanDrasek noted that in her department they have a weekly seminar series conducted by the faculty and do not need outside speakers.

One thing that is troublesome, Dean Bloomfield said, is the idea that training in ethics and responsible conduct is a central administrative idea while faculty and departments are only interested in their own disciplinary area. Ideally, faculty, students, and departments will say that ethics are important to the discipline and should be something they talk about on a regular basis. Professor Brezonik agreed but said there are also University community issues that transcend disciplines. There are slight differences across disciplines, he agreed, but authorship is authorship, for example. Some point to the Academic Health Center and say that the University is doing this because of what happened there--but they do not reflect on problems in their own fields. Attendance at cross-college functions also allows one to bring ideas back to one's own department, Dr. VanDrasek pointed out.

Professor Balas recalled that his department had held a seminar with a lawyer that had generated a lot of conversation--and said that no one would have gone to such a seminar outside the department. How can the Committee encourage the sponsorship of such seminars?

Professor Balas asked if the Committee should comment on the draft proposal. Professor Brezonik said that was its prerogative and they would consider any information the Committee provided. It was moved and seconded that the Committee support the proposal.

Professor Dahlberg asked if this was something the University is saying must be done on a continuing basis, rather than a requirement passed along from NIH. Professor Seybold said the policy came from the faculty governance system, not the central administration. This implements the continuing education requirement, Professor Balas added. Was the requirement for initial training from the NIH or the Senate, Professor Dahlberg asked? Federal agencies broadly want the training to occur, Dr. Hamilton said. The policy institutionalizes the requirements, Professor Balas said. The University is not on exceptional status now and does not want to be again, Professor Dahlberg observed; does this help keep off exceptional status? It is one element, Dr. Hamilton said. The conflict review committees are also a part, Professor Balas noted. The question is whether these efforts are taking care of the extremes, Professor Seybold commented, to which Professor Dahlberg replied that the extremes always create the problems. These efforts help everyone in the middle as well, Professor Seybold maintained.

Is not this part of a national trend, of which the University is a leader, Dr. VanDrasek asked? It is a national effort, Dr. Hamilton agreed. The University is a leader, Professor Brezonik said, but it is not alone; Michigan and Stanford, for example, are also equally involved. In response to a question by a Committee member about the John Najarian case, Professor Brezonik observed that Dr. Najarian might have done what he did even after responsible conduct of research training but others who worked with him would have raised questions and stopped what happened.

Professor Johnson asked if they were following a template or making things up as they went along. To the extent it is the latter, he said, are they doing things like what is being done at Michigan or are they in contact with other universities to learn what they are doing? Does the University's effort correspond to what other institutions are doing? There is no template, Dr. Hamilton said, but the University's activities are consistent with what is going on elsewhere--actually, the University is far ahead of many institutions. Some are ahead of the University (such as those that require an exam on which one must obtain a score of 100% or the training will not be counted as complete). The University's training covers the same points as the exams do elsewhere, Dr. Hamilton affirmed.

Mr. Schumacher commented that federal lawyers believe the bad apple is a rare case but one that training programs will not stop. They look at institutional efforts to prevent unethical conduct, which is another reason it is important to implement the training. Part of EGMS is an extensive oversight process of financial and other transactions--the Office of Oversight Analysis and Reporting, headed by Ms. Schumi, is the oversight agency. They sample transactions to catch things that are being done incorrectly. If someone is determined to commit fraud, however, he or she will be difficult to catch (at least right away). The University was characterized as having a pervasive attitude of non-compliance when it was put on exceptional status, Mr. Wink commented; one hopes that is gone but a bad apple can still happen.

The motion was approved 10-0 with two abstentions.

3. Federal Demonstration Partnership

Professor Balas next welcomed Professor Konstan to the meeting to discuss his impressions of the Federal Demonstration Partnership (FDP), to which Professor Konstan is a representative of the University faculty.

Professor Konstan reviewed briefly the history of the FDP, noting that it is presently in its fourth series and includes a growing set of research universities and explaining that its goal is to get rid of unnecessary administrative hassles. He said he originally thought that the situation, in terms of federal regulatory burdens, was getting worse each year; having participated in the FDP, however, he now realizes that things were much worse in earlier years.

As the FDP enters its fourth phase there are some significant factors worth noting. First, the University of Minnesota is a member (it could not be before because of its exceptional status). Second, faculty are now getting more actively involved about items of concern to faculty (such as getting predictable visas, reduction in restrictions on "sensitive but unclassified" research, burdens on the use of subjects in research, and dealing with the hoops that institutions and faculty must go through in electronic research administration).

The "Demonstration" in FDP means that some of the participants in the FDP agree to a demonstration of a proposal to learn if it works. The hope is that the participants can demonstrate that nothing horrible happened as a result of the change but that it reduced workload. If so, the change is open to the entire partnership and then becomes part of general agency routine. The University is not part of such a demonstration now, Dr. Hamilton said, but it may participate in projects related to effort certification, electronic research administration, and other streamlining activities.

Professor Konstan spoke about the value of the FDP meetings. He said he learned that he had had no understanding of the burdens due to federal regulations as well as the institutional regulations that are NOT imposed by the federal government. There is much that institutions can learn from each other, he said, about what is the common enemy, what is good, what protects the taxpayers.

Professor Konstan said he would be happy to carry to the FDP a message from the faculty at Minnesota about burdensome regulations they deal with. What kinds of things are suitable for the agenda, Professor Johnson asked? Universities may implement responsible conduct of research training in different ways that the faculty struggle with; would that be a legitimate topic? If the University is doing something burdensome but that is not required by federal rules, that would be inappropriate, Professor Konstan said. He said he was surprised that the group had latched onto the visa issue--it is not a federal rule or regulation but the way they are handled in consulates affects research. The responsible conduct of research training is enough related to federal regulations to make it a legitimate topic. Professor Konstan said any effort tied to federal regulations is fair game.

The faculty are a new element in the FDP, Dr. Hamilton reported; earlier it consisted of administrators talking to administrators. The faculty at recent meetings were outspoken and there were a number of them present; they provided a good voice for the faculty. At the same time, there are things that happen as a result of the FDP that may benefit Sponsored Projects Administration more than the faculty, although some things carry through to the faculty such as no-cost extensions of grants. He said he was very hopeful that the faculty would be able to help in the effort (e.g., on effort certification, which costs the University \$2 million per year, driven by the Office of Management and Budget; there was to be a demonstration project but it was cancelled by OMB two weeks before it was to begin. There might be another, but not unless the faculty yell loudly enough).

Professor Konstan said it isn't enough for people to be trained on the rules. They speed while driving even though the speed limit is well-posted; if regulations can be designed and explained so faculty and staff agree they are rational, people who normally follow rules will do so.

Asked how he was selected, Professor Konstan said Dr. Hamilton has asked him; he said he had made it clear that if the Committee wished someone else to fill the role he would be happy to step aside.

Are some federal agencies more receptive to suggestions than others, Professor Balas asked? They are, and some are more capable, Professor Konstan said. NIH and NSF actively try to make things happen; others do not. Over the long term, the smaller agencies will follow the lead of the big ones; they are trying to be sure that the big agencies are not inconsistent with each other and with the systems that universities will have in place.

Professor Konstan said he talked at the meeting about getting a one-page flier summarizing the issues so that they can have time for comment. Nothing moves quickly, he noted. The University is in

better condition than many because it has this Committee; it is his intent to forward issues to it and let the Committee decide if they want to discuss them. He said he would bring to the Committee items that appear on the agenda of the next meeting, in early May.

Professor Balas thanked Professor Konstan for joining the meeting, and adjourned it at 2:50.

-- Gary Engstrand

University of Minnesota