

Minutes*

**Senate Research Committee
Monday, January 24, 2005
1:15 - 3:00
238A Morrill Hall**

Present: Gary Balas (chair), Mark Ascerno, Dianne Bartels, Richard Bianco, Victor Bloomfield, Christopher Cramer, Dan Dahlberg, Sharon Danes, Genevieve Escure, Steven Gantt, Michael Hughey, Paul Johnson, Mark Paller, Mira Reinberg, Thomas Schumacher, Maria Sera, Charles Spetland, George Trachte, Barbara VanDrasek, Jean Witson

Absent: James Cotter, Robin Dittman, Kathy Ensrud, David Hamilton, James Luby, Ryan Lukas, James Orf, Virginia Seybold, Michael Volna

Guests: Melinda Sewell, Ed Wink (Office of the Vice President for Research)

Other: none

[In these minutes: (1) report of the chair (searches, schedule); (2) update on the institutional conflict of interest policy; (3) animal care and use policy; (4) survey of IRB users; (5) brief updates]

1. Report of the Chair

Professor Balas convened the meeting at 1:15 and began by noting the sessions with the candidates for Vice Provost and Dean of the Graduate School. He urged Committee members to attend and prepare evaluations; the Committee could decide later if it wishes to send a Committee response or if individual Committee members will submit their assessments to the Provost.

The update on University Enterprise Laboratories will be scheduled later, in order that Dean Elde and Mr. (Peter) Bianco of UEL can participate in the discussion.

2. Update on the Institutional Conflict of Interest Policy

Professor Balas turned then to Mr. Bianco to lead a discussion of the institutional conflict of interest policy. Mr. Bianco noted that the Regents' policy, which the Committee reviewed earlier, involved no significant change since that review and it is expected to go to the Board later this spring. The administrative policy, intended to implement the Regents' policy, is new. He distributed copies of the draft policy and appendices and assured the Committee he did not expect responses at this meeting; he suggested that Committee members review the draft and that it be on the agenda at an upcoming meeting for discussion and vote.

He recalled that the process for development of the policy started about a year ago. The Board of Regents asked that a policy be developed; Interim Vice President Hamilton appointed a committee that

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has been writing the policy since. The administrative policy is not limited to research activities; it is a broad policy that covers gifts to the University, investments, technology transfer, purchasing, protection of human subjects, and the actions of senior officials.

How have things changed, Professor Balas asked? There is no institutional conflict policy now, Mr. Bianco said; this is new. There is an INDIVIDUAL conflict of interest policy, in place since the mid-1990s, which has been successful. This policy speaks to INSTITUTIONAL conflicts of interest and holds the institution to the same standards as individuals. For senior officers, there is some overlap in the two policies. Will there be a form like the REPA with this policy, Professor Balas asked? There will be questions on the form for senior officers, Mr. Bianco said.

Are there any implications in the policy for incubators, start-ups, etc., Professor Johnson asked? They are very interested in them, Mr. Bianco said, and the policy will cover, for example, a dean who is also director of a start-up company in which the University invests. They are looking closely at these relationships, which create a flag for attention (not a red flag, just a flag).

Was the impetus for this policy a problem or because the Regents felt there was a lack of oversight, Professor Balas inquired? Neither, Mr. Bianco said; it is a national issue; all major research universities are working on a policy.

Will financial relationships be included on consent forms for clinical trials, Ms. Witson asked? The IRB will make a determination about whether disclosure is required, Mr. Bianco said.

Will there be a committee that looks at the relationships, Professor Balas asked? What if the President has a conflict of interest, and a committee is composed of subordinates to the President—will the committee say the President did something wrong? Will a committee include outside representatives and peers of the President? Mr. Bianco noted first that he will STAFF the committee, not serve on it. It will have high-level administrators, Regents' Professors, high-level faculty governance representatives, and outsiders; it will be like an IRB panel. He will report to the President on the work of the committee, Mr. Bianco said, and if the President is involved in a potential conflict, the matter will be brought to the chair of the Board of Regents, through the General Counsel.

Does the policy cover only financial relationships, Professor Balas asked? It is wider than research, Mr. Bianco explained. The committee and disclosure process are intended to provide advice; its work is not binding. It is a mechanism to find a way out of a potential problem or to do something.

Dr. Paller asked why the policy does not include research that does not involve the use of human subjects. Ms. Sewell explained that there is no threshold requirement for conflicts involving use of human subjects; for other research, covered by this policy, the threshold is \$50,000.

Professor Bartels asked if, when an individual conflict of interest form is submitted and review shows a patent could make millions of dollars, the form would also call for review of the activity as an institutional conflict of interest. It need not be a dean who makes a lot of money for the University, she observed. There would be an automatic flag, Mr. Bianco said; they are still working on that part of the policy.

Does the policy cover the Board of Regents, Professor Balas asked? It does, Mr. Bianco said, and the committee appointed pursuant to the policy will look at potential conflicts for Board members if the Board wishes. The Board does have its own Code of Conduct policy, he noted, and Board members are not University employees. They will disclose any conflicts to the General Counsel, who would bring them to the committee, if appropriate.

If an individual has a conflict of interest (e.g., receives money to do research for a company that he or she owns stock in), does that mean it is also an institutional conflict of interest, Ms. Witson asked? It does not, Mr. Bianco said; it is an institutional conflict only if a dean or higher-level administrator is involved.

The policy will be brought back for review and vote later this spring, Professor Balas concluded. He urged Committee members to send any questions to Mr. Bianco, preferably in advance of the next Committee discussion.

3. Animal Care and Usage Policy

Mr. Bianco next turned to the Animal Care and Usage policy. The Board of Regents regularly reviews its policies; there were few changes in the animal care policy. One major change is the improvement of the Research Occupational Health Program (ROHP). The Institutional Animal Care and Usage Committee (IACUC) has been certified for a long time, but in the last review, the University was cited for having an inadequate occupational health program for the people who work with animals (as was just about every research university). The point is to ensure that someone is watching out for the welfare of the people who work with animals. Mr. Bianco distributed a handout highlighting what the University is doing in this regard.

Were faculty and researchers involved in the development of the program, Professor Balas asked? They were, Mr. Bianco said, as well as veterinarians, Environmental Health and Safety officers, and representatives of his office. The University has had a program, he noted; these changes are intended to make it better.

Are there questions being raised at the national level about animal care, Professor Balas inquired? Does he expect more regulation? Mr. Bianco reported that the University does TB testing to protect the animals, and there is huge effort to protect both patients and animals, especially as researchers work with more dangerous materials. He said he did not expect more regulation in animal care specifically but predicted that there will be more regulation in general. With respect to animal care, the federal government trusts AAALAC (Association for Assessment and Accreditation of Laboratory Animal Care), a voluntary organization that maintains standards, of which the University is a member and which has certified the University's programs. In response to a question from Professor Balas, Mr. Bianco said that the University pays for any shots that employees need to have in association with their work with animals.

Will researchers need to be updated every year, and have to go through training, Professor Balas asked? There will be an annual survey, and training for new employees, but they are not contemplating annual training, Mr. Bianco said.

Even if there were no AAALAC, this is the right thing to do, Mr. Schumacher commented. Everyone must understand that the University is doing the best it can to protect its employees. This is something it can do and must do.

4. Survey of Institutional Review Board (IRB) Users

Professor Balas recalled that there had been rumblings about the IRB and obtaining exemptions and approvals for research. As a result, the administration and the Committee commissioned a survey of IRB users. The results were discussed by the Committee last year. There were a number of positives in the results, and general confidence in the IRB, but also a number of unanswered questions. Where do things stand, he asked, and what has changed in terms of how the IRB does its job?

Mr. Bianco began by commenting that the data from the survey were lost, unfortunately, but the survey was very positive about the IRB. There is nothing that can be done at this point except to replicate the survey, which should be done anyway because the first one provided a baseline.

As he read the data, it was the senior faculty who were more dissatisfied than were junior faculty. There was a concern about consistency of answers, about not using electronic means of communicating decisions, and about whom to call with questions. One problem was that there has not been a distinction drawn between federal regulations and local policies; the senior faculty who were upset about the IRB, it turns out, often were upset with the federal regulations, not with University policy. In those cases, Mr. Bianco said, they advise people to contact their Congressional representatives because the University cannot ignore federal regulations.

Mr. Bianco provided the Committee a summary of the survey results prepared by Professor Oakes and others. He said he assumed the results would be much more negative than they were. What have they done? They have improved communication with faculty, almost all communication is now electronic (researchers can have immediate approval and need not wait on hard copy), they have changed the social science panel to respond in particular to concerns about student projects (and have created a panel for student research), they changed the makeup of the panel to include more doctors (departments have been getting physicians to serve, which helps review quality for clinical studies), and have improved telephone service. They have also established a clinical research task force, a faculty consultative group composed of high-profile clinical researchers, to meet periodically with the IRB. This Committee has a representative on the task force (Professor Bartels). They will discuss the issues the survey suggested need to be addressed. Mr. Bianco repeated his point that the survey should be conducted again, to see if they have made improvements.

Professor Balas said that when the Committee was told recently what one must do in order for research to be exempt from IRB review, including filling out an 8-page form, it was told that there was need to keep track of research. If faculty were told that they should provide the information to help the University keep data it needs and to help the IRB improve its service, they would be more likely to provide it. Professor Escure pointed out that one needs an exemption to receive federal funds; it is not an option. The question for some, Mr. Bianco observed, is whether all the information is required or if some is optional. He said he did not know the answer to the question but would find out.

One source of dissatisfaction is not that there is one 8-page form but that there are multiple 8-12-page forms that must each be filled out, Dr. Paller maintained. He said he understood that the University

was moving to a uniform system and that the IRB received the money to do so. What happened? Mr. Bianco said he did not believe it would be possible to have one form; it would be too confusing, and there is a need for parallel reviews of proposals, not sequential reviews. Why could not the face page information be provided for all the forms, Dr. Paller asked, so that the same information would not have to be provided repeatedly? Mr. Bianco said he had no problem with that idea but that they do not have the money to do it. That would save 1-2 pages, Mr. Wink commented; for thousands of faculty and researchers, Professor Balas responded, who must spend time on all these forms, it is a lot of time. Why cannot the forms be populated with information that is already in the databases? Is that not the goal of e-research central, Mr. Bianco asked? The project has stagnated because of a lack of funding.

Professor Sera commented that the social science forms for the IRB have gotten much longer and some of them have redundant questions. With increased regulation there has been more added to the forms, but has anyone looked at the forms to eliminate redundancies? Mr. Bianco agreed that was a good idea but that no one has every been charged to do so. Ms. Witson asked if, given that there is no funding to create a single application, whether groups could be urged to drop duplicate questions—and there IS a lot of duplication.

Is the IRB benchmarked vis-à-vis other institutions in the way it handles its work, Professor Balas asked? They are looking at other programs, Mr. Bianco said, and there is a network of institutions like the University (of which there are about 10) that work together. None have identified solutions to the problems that have been discussed here. If they COULD be solved, that would go a long way to reducing faculty ire, Professor Balas commented. Mr. Bianco said that incoming Vice President Mulcahy needs to hear these concerns as well. Faculty time keeps getting lost, Professor Balas, so it is little wonder that faculty do not want to follow all the regulations. Mr. Bianco commented that he does research involving animals and is as frustrated by the forms as anyone. It is, however, hard to effect change; the system is overloaded.

If the survey is done again, are there additional questions that should be asked, Professor Balas inquired of his colleagues? It was agreed that the previous survey would be circulated to the Committee for review. (It was noted that the IRB will seek IRB approval for the survey, although technically the approval might not be required because it is not doing research, it is working for the improvement of business practices. They will seek an exemption, Mr. Bianco assured the Committee.)

Professor Escure said she would like to see oral consent added to the form, in addition to written consent, so that in some cases oral consent may be part of the application process without resorting to lengthy explanations.

Professor Balas thanked Mr. Bianco for the discussions.

5. Updates

Professor Balas reported that the secrecy policies and procedures will not be ready for February but will be presented later. Members of the Social Concerns Committee will be invited to join the discussion because they are interested in the topic.

At the next meeting Vice President Mulcahy will join the Committee.

Even though Interim Vice President Hamilton was absent, Professor Balas extended a heartfelt thanks to him for the very productive working relationship the Committee had with him during his tenure in the vice president's office.

Professor Balas adjourned the meeting at 2:05.

-- Gary Engstrand

University of Minnesota