

Minutes*

**Senate Research Committee
Monday, November 22, 2004
1:15 - 3:00
238A Morrill Hall**

Present: Gary Balas (chair), Mark Ascerno, Dianne Bartels, (George Green for) Victor Bloomfield, James Cotter, Sharon Danes, David Hamilton, Michael Hughey, Paul Johnson, James Orf, Mark Paller, Virginia Seybold, Maria Sera, Charles Spetland, George Trachte, Jean Witson

Absent: Aleksa Babic, Christopher Cramer, Dan Dahlberg, Robin Dittman, Kathy Ensrud, Steven Gantt, James Luby, Ryan Lukas, Mira Reinberg, Thomas Schumacher, Barbara VanDrasek, Michael Volna

Guests: Professor Joseph Konstan (Federal Demonstration Partnership); Winifred Schumi, Ed Wink (Office of the Vice President for Research); Assistant Vice President Richard Bianco, Moira Keane (Office of Regulatory Affairs), Professors J. Michael Oakes, Sarah Jane Schwarzenberg (Institutional Review Board); John Engelen (Director of Federal Relations)

Other: none

[In these minutes: (1) effort certification and the Federal Demonstration Partnership; (2) Institutional Review Board update; (3) update on federal issues; (4) resolutions]

1. Effort Certification and the Federal Demonstration Partnership

Professor Balas convened the meeting at 1:15 and welcomed Professor Konstan and Ms. Schumi to discuss effort certification and the Federal Demonstration Partnership (FDP).

Professor Konstan recalled for the Committee that the FDP is a collection/partnership of about 100 research universities plus the federal agencies that fund them plus a few other organizations; the goal of the FDP is to try to streamline the process for giving out and reporting back on funding from the government to the universities for research. A lot of work has been done on electronic grants administration. Four types of people are invited to attend FDP meetings, including one faculty representative from each university (he is the faculty representative for the University of Minnesota, and has been recently elected to chair the faculty representative group for the next two years). The faculty representatives look out for the interests of the principal investigators across all fields. There are also administrative representatives from each institution (typically vice president for research offices), technology people, and agency representatives. Assorted vendors also attend as observers/guests.

* 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.

The FDP is moving slowly on effort certification, Professor Konstan reported. Faculty objections to effort certification center around four issues:

- They object in principle; they get the work done, so why does anyone care how it got done? This argument is mostly lost; the federal government will not allow someone to get four grants that each require a 45%-time commitment.
- They object to dividing their time into small chunks.
- They object to the percentage of time requirements.
- It is impossible to certify effort for certain people because they do not know the information.

There have been various demonstration projects that have gone nowhere (such as payroll certification—you certify you did the work because you took the money). One proposal is to tie effort certification to the annual reporting process; the PI certifies that all the people contributed appropriate effort and time (which in some cases is difficult for the PI to know). Another big issue is the role of investigators other than the PI (e.g., the names on grants, centers, etc.); NIH is willing to assign credit where there are intellectual contributions from more than one person).

What is the liability for people who certify the work of others, Professor Johnson asked? They should know the work they have done, Mr. Wink said. If they do not, then someone who does know about the work should certify the effort; that could be the lead scientist, a lab supervisor—whoever makes work assignments. There is a 4-5% tolerance. In the case of graduate students, Professor Konstan added, 100% time is the time they are paid for. Effort certification can be more difficult for employees who are shared across projects and the employee himself/herself may not know how much time was allocated to various projects.

Professor Balas asked Professor Konstan what he saw as the best solution to the issues that surround effort certification. Professor Konstan said there were two stages. One, what can be done that does not require any additional federal assent? There is faculty support for annual certification and spreading summer across the year (recognizing that often much research is done during summer months and less during the academic year) and term-of-appointment certification for term employees. Two, in the long run, most faculty believe the whole thing is silly, Professor Konstan said. If it were possible to get a demonstration for OMB that nothing terrible happens if the effort certification rule is relaxed, and that institutions would certify that no one was paid more than 100%, it would be better to have reporting once per year by the institution along with an end-of-project report affirming that people did what they were supposed to do. But that may not be possible because a lot of people in the federal government believe that universities are out to get federal dollars and they do not trust the universities or the faculty to follow the rules.

In response to a question about how this differs for grants vs. contracts, Prof. Konstan said that there are two types of contracts. One is fixed price (where the funding organization does not care about the costs, and there is no extra funding for increased prices); the other is cost-plus (where the funding organization requires an accounting). Universities are subject to both—they have fixed-price contracts, with no money for increases, and they must account for every dollar so the government knows it got value

from the grant. Answering the latter question is hard; unless there are evaluation panels to review the work after it is completed, one cannot tell if the grant expenditure was worth it.

Professor Orf said that it was implied that if one works on weekends, that is part of someone's efforts and affects how much time should be devoted to a grant. All work within the scope of employment is part of one's total effort, Professor Konstan said. If one works a 40-hour week, a grant commitment of 10% equals four hours per week. If one works 60 hours per week, that same 10% commitment is 6 hours per week. If someone puts in 200 extra hours to help a student with a dissertation or to do some other work in a short period, that time becomes part of the total effort and the 10% no longer equals four hours—and the government says the person owes more time. The alternative is also irrational, he said; if one works 55 hours per week, but people are expected to bill 40 hours per week to grants in order to pay their full-time salaries, the University gets the rest of the time free. The definition of voluntary activities is unclear, and often determined by the individual. For faculty not employed by the University in the summer, it is a volunteer activity if one does research with a student, for example. The correct interpretation of the regulations now is that one adds up everything one does in all hours, it all counts the same, and one then owes X% of that total to the grant.

Professor Orf said that he has an appointment that is 80% research and 20% teaching, but when he does effort certification, the work without teaching adds up to 100% so the teaching does not show up. There should be a line for administrative/institutionally-supported efforts; that line could have 20%, Professor Konstan said. Professor Orf also noted that he is listed on some grants and does not receive any money for his lab from them, but he does contribute intellectually to those grants; the time falls in the 1-3% range. Is that appropriate? It is, Professor Konstan said, and would not have to show up on effort certification unless there is committed cost-sharing.

Mr. Wink said that the University has the capability to provide annual certification for faculty—but there has been a lack of enthusiasm for annual certification when they have surveyed the faculty. There is a preference for more frequent certification; people say they do not want to have to remember what happened 10 months ago. Who did they survey, Professor Balas asked? The faculty in his program can remember! This is something the Committee should discuss, he said. He said he would be surprised if faculty did not sign up for annual certification. There could be a problem with graduate students who are appointed for different times, Professor Konstan said, but there should not be for faculty themselves. Vice President Hamilton said that a survey of department administrators did not care for annual certification because it would mean keeping records up to date. It may be that there would need to be two different cycles of reporting, one for faculty and one for graduate students, Mr. Wink said; Dr. Hamilton said it would be necessary to have the funds available to do such reporting, which would not be technologically trivial. Professor Balas said the University should not do something because the funds are not available; he expressed frustration at the faculty being told they have to do additional work because of a lack of funds and said the faculty need to stand up and say this is not acceptable.

Professor Balas thanked Professor Konstan for his report.

2. Institutional Review Board (IRB) Update

Professor Balas next welcomed Assistant Vice President Bianco and Ms. Keane to the meeting to discuss the IRB and its work. He recalled that last time they met with the Committee, they presented survey results; Committee members were interested in a follow up.

Mr. Bianco said he wished first to explain the work of the IRB, the source of its authority, and its milestones and achievements. He also introduced the chairs of two of the IRB committees, Professors J. Michael Oakes (Epidemiology), who chairs the social science panel for student research, and Sarah Jane Schwarzenberg (Pediatrics), who chairs one of the medical panels. The IRB—the human subjects committee—is established by federal statute and regulated by the Office for Human Research Protections (OHRP). OHRP is an arm of the Department of Health and Human Services (DHHS) but any institution that receives federal funds for human subjects research must assure OHRP that it has a functioning IRB. The IRB is empowered to deal with all human subjects research irrespective of the source of funds; each IRB carries out its regulatory authority in accord with local norms, within the context of federal law. IRB panels are composed of faculty and staff and review protocols for the use of human subjects in research. The panels are distinct from the STAFF of the IRB, which provides support to the committees (including animal care as well as human subjects research). People who are upset with an IRB ruling often focus on the staff rather than the faculty chairs of panels or on him, Mr. Bianco said, although they should focus on the latter two rather than the IRB staff.

The University of Minnesota IRB was accredited last April, the largest research university in the world to be accredited. Only nine institutions had been accredited at that time, so this is a significant distinction.

They have been working for a number of years with Vice President Hamilton to enhance the service aspect of IRB activities for faculty, Mr. Bianco told the Committee. In that regard, they are moving to primarily electronic service. They have received funding from NIH to enhance the systems, Ms. Keane reported, and will roll out phase one of the electronic system in January.

The IRB has seven panels, Mr. Bianco said—four in medical fields, one in the social sciences, one in the social sciences dedicated to student research, and the executive committee, which functions as a panel. The student panel is the first in the country and is seen as a model; it deals with the students as mentors. Related to the panels and infrastructure, the goal in the Academic Health Center is to dramatically increase the number of clinical trials (increase by a factor of three). The infrastructure will need to keep up with that work, including an expanded IRB and electronic service.

The challenge to the IRB is that the University is considered one of the top three public research universities and wants to increase the number of clinical trials and must therefore increase its infrastructure. There have been a number of unfunded mandates from the federal government, which have delayed the service improvements they hoped to achieve, Mr. Bianco said (such as HIPPA compliance, the IRB accreditation, adverse event reporting, and so on). The Office of Regulatory Affairs has a clinical monitoring program to actively ensure compliance, but it does so by way of assistance, not policing.

The major problem they face is that there are not enough M.D.s on IRB panels, Mr. Bianco told the Committee. That lack prevents an adequate review of proposals, and they are near the point where the federal government will require them to stop reviewing proposals if they do not have more M.D.s. They are facing a crisis, he said, and he has met with the clinical department heads to raise the issue. Professor Schwarzenberg echoed Mr. Bianco's point about the insufficient number of M.D.s; she said that they do not have enough doctors participating to ensure adequate review so they will have to limit the number of proposals they can review. She agreed that it is hard work, and the people who participate are

volunteers who contribute several hours per month for which they receive no credit in the institution. They only participate because they are dedicated to the protection of human subjects. This is a national problem, Mr. Bianco said; physicians are expected to generate more patient dollars and more grants, so they have no time to assist with the IRB process.

Professor Schwarzenberg said that she started out very angry with the IRB, sure that it was composed of idiots who did not understand her proposal. Being on an IRB panel has made her aware that there are enormous differences in writing proposals—and her ability to write them has been significantly improved by her service. There is much to be gained by serving on an IRB panel, she said. For the long term, there is a need to provide career development programs for junior faculty that can include building in time for service on an IRB panel, Dr. Paller said. That is not an immediate solution, but if the research enterprise grows, it must have the support of all faculty. Young investigators are welcome, Mr. Bianco said, but they also need senior investigators as well. Professor Schwarzenberg said she believes that if one is doing a substantial amount of clinical research, one owes the time on an IRB panel because it is helping faculty do their research. Faculty owe it a couple of years.

Is there a way to split the load, Professor Balas asked? That can be arranged, Ms. Keane said. Unless there is a huge number of proposals, Professor Schwarzenberg said, reading the proposals takes 6-8 hours plus a 2-hour meeting per month. It is doable. Professor Bartels asked if there is any chance of creating a reward for serving on the IRB. They need people who understand clinical research and clinics; could clinical research nurses serve? Ms. Keane said they are struggling with the reward system. There are no funds to pay people directly and she was not sure that was a good idea. There are intrinsic rewards. They are exploring the issue but do not have an answer. It is difficult to put in time that does not count, Professor Bartels observed. And some people are penalized for doing so, Ms. Keane added; some have seen their salaries reduced as a result of participating on the IRB.

This is a top-down problem, Professor Balas maintained. Senior Vice President Cerra, Associate Vice President Paller, and the Academic Health Center deans need to step up to the plate or recognize that there will be limits on the number of proposals that can be reviewed. He said he was tired of hearing people preach to the faculty about their obligations but provide no reward. This is like reviewing papers—it is a professional obligation and one does it. The University will not remain among the top three public research universities if it begins to lose research funding because of the inability of the IRB to review proposals.

The reward system is faculty driven, Dr. Paller responded. Who determines the content of the 7.12 statements, he asked? And who makes up the promotion and tenure committees? The University could not pay enough to get people to serve on the IRB. The faculty must say that they value this kind of service. Until it means something, and one gets credit for the service as an assistant professor, the appeal to serve will go nowhere, he predicted. The burden can't be placed on the dean, who can only override a department decision; this must be something the faculty uniformly agree is valuable. And the issue is now before faculty governance, so there is the opportunity to make a statement.

Professor Oakes said that one of the more controversial parts of the IRB has been in its review of social science proposals. Social science faculty have been annoyed, especially in economics, sociology, and anthropology, because they see the IRB as impeding their research. They frequently deal with miscommunication errors and misunderstandings, he said. What is hardest to get across to faculty is that the IRB process is a peer review system. This is not administrators reviewing proposals; "it's us," he said,

and they serve on the IRB panels for no gain. He said that he is an assistant professor and he was told not to serve on the IRB panel, that it was a waste of time. That is not true, he said, and he has gained a lot of insight through his service.

There are also hidden benefits to the IRB, Professor Oakes said. Recently a faculty member made an error in doing research and angered the community with which he was working; the community threatened to not allow additional research in the community. If it were not for the IRB administrators explaining that the error was not University policy, the research would have been halted.

They are making progress in working with students. They cannot take six months to review a proposal; the process is not the same as it with faculty, Professor Oakes said.

Professor Oakes also commented that Mr. Bianco and Ms. Keane undersell themselves; this is the leading IRB in the country, he said. They recently sent 20 people as invited speakers to a national meeting on IRBs. Mr. Bianco said the credit goes to Ms. Keane; the University has the most highly-certified staff in the country. Senior Vice President Cerra and Vice President Hamilton have helped the IRB financially, but the faculty time contribution cannot be addressed so easily, he said. [Note: No funds have come from the Academic Health Center to fund the IRB.]

Professor Balas repeated that the leadership must stand up and say this is important. The same is true of faculty governance, he added; they must say it should be part of faculty obligations. Why not create another panel, Dean Green asked? That would require an additional two FTE employees, Mr. Bianco said; they need two per panel. Both Professor Oakes and Schwarzenberg said the problem is a lack of people to read proposals and more proposals. Each panel needs the requisite expertise. Ideally, for a medical panel, each proposal is reviewed by one medical person and one person from outside the field, Professor Schwarzenberg said.

Professor Balas next recalled that last spring the question of IRB regulation of use of public data came up (e.g., census data on the web). There is variation across the Big Ten in how this is approached, he said, and he went to a couple of web sites with data; all one need to do is sign up and download the data without charge. He said it is their understanding that such research is exempt because the data are all public, in the public domain, and anonymous. The fundamental questions one must ask when asking if an activity needs IRB approval, Ms. Keane said, are, first, is it research? and if so, is it human subjects research? She said she hears complaints, for example, about oral history with one person; that does not meet the threshold. They hear questions about public databases; the IRB does not have jurisdiction in the use of public databases. If individuals are not identifiable, the IRB does not grant an exemption—because it does not weigh in on the research at all; she repeated that it does not fall under the IRB jurisdiction. At other institutions people need to go through the IRB, but they have consulted around the country, including with the federal government, and concluded that some research using public databases is outside their jurisdiction.

With respect to census data, Professor Oakes said, publicly-available, down-loadable data sets that have no identifiable data are automatically exempt. He does tell colleagues and students, however, that it only takes about 3 minutes to get IRB approval. The research is exempt, but the cost to make sure is very small relative to the benefit.

So, Professor Balas concluded, de-identified data is outside the scope of the IRB and one does not have to go to the IRB to use census data. The model is that an independent office must decide, Ms. Keane said, and a telephone call allows them to say something is outside IRB jurisdiction. She said they would like to have that call. Mr. Bianco cautioned that before resolutions or criticisms are adopted, sometimes in a vacuum, it is important to ask about the systems that are in place. It is more helpful to have a dialogue than to pass resolutions that may be ill-founded, he said. Ms. Keane added that they are not looking for work; they will see about 2000 or more proposals this year.

Where do market surveys fall, Professor Ascerno asked? That depends, Ms. Keane said. If it is needs assessment for program development, it is not research. If the intent is to draw broader conclusions, then it is covered by IRB regulations.

Professor Schwarzenberg said she had seen one tragic event in a research project where the researcher did not believe IRB approval was needed; as a result, the research could not be published. One can get a prompt answer, she said, and it is better to ask.

Professor Sera said that she has complained in the past, and perhaps it was to the wrong person because it was the staff name on the letter. Mr. Bianco said they have thought at length about whose name should go on the letter; there is a rationale for the staff signature. Part of it is history, Ms. Keane explained, and after a 2-4-hour meeting with 70 action items, the staff compose the correspondence and can often field questions and can more readily get to the executive committee. And they are in the office every day. They receive about 50 calls per day, of which about 20% are upset with an IRB decision. That is not out of the norm, and the investigators are told by the IRB panel to make their work better.

Professor Sera said she was concerned about a different panel for social science work for students. It should not matter if the research is done by faculty or students; the standards should be the same. The review standards are identical, Professor Oakes said—they reflect federal law. What is different is that typically these are training programs, so students are not doing ground-breaking research; there is risk to the research, as with any research, but there is usually not a lot of benefit from it (unlike what is supposed to be the case with faculty research proposals). In the case of the students, they do not say "do not do the research because it is not worth it," but they remain sensitive to the risks. The standards are the same.

Professor Sera then said that they hear complaints about problems in the social sciences; do they do anything about them? They identify all of them and do something, Mr. Bianco assured her. They need expertise on the panels, Ms. Keane said—they need faculty involved to address concerns. They have turned around a lot more proposals because they have increased the number of faculty participating on panels.

Professor Balas thanked Mr. Bianco, Ms. Keane, and Professors Oakes and Schwarzenberg for joining the meeting and making their report.

3. Update on Federal Issues

Professor Balas turned now to Mr. Engelen for a report on federal issues.

Mr. Engelen began by informing the Committee that up until June of this year, he was "federal relations" for the University; his office is at the University and he commutes to Washington. He organized 275 meetings in Washington, hosted 60 Congressional staff on visits to University campuses, and tries to schedule at least two visits by each member of the Congressional delegation to a University campus each year. As of July 1, he has an assistant director of federal relations and a communication professional. His office will provide monthly updates, information, links, and has built a federal relations website, www.umn.edu/fedrel.

Congress is still in session as a lame duck. It is supposed to act by October 1 on 13 appropriations bills that keep the government running but had only acted on 4. The other 9 were all completed in the past weekend, with a 1000+-page document. Mr. Engelen expressed doubt that all members of Congress had read the bill and he noted that there are already controversies about its provision; some items were never talked about in committees. Who knows what's in the bill, he commented.

The federal budget is about \$2.4 trillion, about \$400 billion in deficit. Congress deals with about \$822 billion in the appropriations process; any spending, tax cuts, deficit-reduction legislation must come from that \$822 billion. Two bills (Homeland Security and the Department of Defense) totaled more than \$400 billion alone, which leaves about \$422 billion for everything else. Mr. Engelen said he was not surprised that Congress did not complete the bills; there is nothing positive and the numbers do not add up. What they do know about the 9 bills that were enacted all together is this:

-- Pell grants were frozen and there was a devastating formula change that will remove funding from up to 100,000 college students.

-- NIH increased \$620 million (about 2.2%). That is the smallest percentage increase since 1986; it will mean perhaps be 200 new grants for the entire country.

-- NSF was cut by \$107 million, or nearly 2%.

-- In general, the news is not good. Department of Energy research increased while Department of Agriculture research funding is flat. The National Endowment for the Humanities increased. If one is doing work that is not homeland security- or defense-related, the news is not good.

-- One other important issue has been visas. There have been a host of issues post-9/11 related to getting international students to campus. The University has been vocal with the Congressional delegation and has spoken with the Assistant Secretary of Homeland Security. His frustration is that while the universities have been vocal about what is wrong, they have been slow to identify good ideas to fix the process while maintaining security. Secretary Ridge met with a number of university presidents last April and said that if they have good ideas, he would work on them. Since then, he reported that there has been some progress and several new initiatives were implemented this summer. In exchange for his commitment, Secretary Ridge asked for a survey of universities to find out if things are better or worse; about 400 universities responded. The results suggest that the new regulations are having a significant impact on new incoming students and the numbers are still going down.

Dean Green noted that for the Graduate School, there has been a declining number of applications but not of acceptances. Some institutions saw increases, Mr. Engelen reported; 55% saw a decline, and

when those that saw no increase are included, 70-75% saw no increase or a decline. The decline is at the front end of the process, Dean Green said, so could reflect decisions internally, outside the United States, and not what the federal government has done. Mr. Engelen said he is working with the Congressional delegation and the higher education associations to continue to address the problems.

Mr. Engelen said that looking forward, he would highlight a couple of things for next year. One, the federal government budget impact will be that universities that want to increase their rankings will have to be more competitive because there will not be new money from federal agencies. Two, the federal government will hold research more accountable and there will be new regulations that will cost money. There will be Congressional push-back on NIH—Congress will want to see positive results of the recent doubling of the NIH budget. There will also be more political correctness on where money is spent. Three, homeland security issues will continue, such as limiting access to research, what is classified or "sensitive but not classified," and new (unfunded) regulations for security enhancement.

There will be debate about for-profit publishers of academic journals and open access. There is a proposal that there must be open access to NIH-funded research six months after it is completed. Breakthroughs in science and technology are straining copyright (e.g., on-line courses) and patent law (e.g., bio-engineering). A related issue is how the University can best preserve royalties when federally-funded research is highly profitable to licensees. Should a research agency be able to recover some of the money, in those instances?

Congress will try to reauthorize the Higher Education Act. The debate will include tuition controls, student financial aid, and focus on the curriculum (the "academic bill of rights").

Professor Orf said the debate about accountability is important. Where is the debate going and will it make things more difficult for investigators? It will, Mr. Engelen responded. There is the potential for new kinds of reporting and a Congressional demand for outcomes. He said he believes Congress has lost touch with the idea of basic research; it has focused on the doubling of the NIH budget, which came about in part from pressure from patient groups and university biomedical groups that lobbied about the importance of health research. Congress will likely ask if there have been new drugs or treatments that resulted from the budget increase. There is a disconnect on the understanding of when benefits will accrue from basic research. What does accountability mean, Professor Orf asked? Accountability to the public for new health care treatments, Mr. Engelen said.

What form will accountability take on campus, Dean Green asked? Proxmire-like "golden fleece" attacks? More paperwork? If one is a Congressional staff member, the best benefit for re-election is Proxmire-like attacks, Mr. Engelen said—identify a grant that does not make sense to the person on the street. Then the agency reacts to the criticism, and the result is all in what the agency does, which is go after investigators and issue more regulations. Or someone might do something wrong, which leads to more paperwork for everyone.

With the California stem-cell initiative adopted, Professor Balas asked what Mr. Engelen hears in Washington. Will they relax the restriction on stem cell lines? Will California be punished? Mr. Engelen said the administration will not relax the restrictions on stem cell lines but the California initiative has started an arms race at the state level. Massachusetts, Wisconsin, and Illinois are looking at funding for stem-cell research. He said believed Congress would not revisit the Bush administration

guidelines on stem-cell research. Dean Green commented that the California initiative takes Congress off the hook on the issue.

Professor Balas thanked Mr. Engelen for his report. Mr. Engelen said that if anyone has questions or wants to know more, they should feel free to call or email him.

4. Resolutions

Ms. Witson moved that the Committee congratulate the IRB on being accredited. The motion passed unanimously and enthusiastically.

Professor Balas moved that the Committee encourage faculty participation in the IRB by serving on panels and that the University make clear that such service is highly valued in order for the University to remain a leading research institution. This motion also passed unanimously and enthusiastically.

Professor Balas adjourned the meeting at 3:00.

-- Gary Engstrand

University of Minnesota