

Minutes*

**Senate Research Committee
Monday, November 21, 2005
1:15 - 3:00
238A Morrill Hall**

- Present: Steven Ruggles (chair), Dianne Bartels, Linda Bearinger, Richard Bianco, Arlene Carney, Sharon Danes, Genevieve Escure, Steven Gantt, Paul Johnson, James Klaas, James Luby, Brian Reilly, Thomas Schumacher, Virginia Seybold, Charles Spetland, George Trachte, Barbara VanDrasek, Jean Witson
- Absent: Mark Ascerno, Kathy Bowlin, James Cotter, Christopher Cramer, Dan Dahlberg, Robin Dittman, Penny Edgell, Jacob Granholm, Timothy Mulcahy, Mark Paller, Maria Sera, Michael Volna
- Guests: Dean Gail Dubrow (Graduate School); Mark Bohnhorst (Office of the General Counsel); Ed Wink (Sponsored Projects Administration); Professors Susan Berry, Michael Oakes, Sarah Jane Schwarzenberg (IRB), Moira Keane, Carol Siegel (Research Subjects Protection Program)
- Other: none

[In these minutes: (1) graduate fellowships; (2) update from regulatory affairs; (3) Institutional Review Board (IRB) issues; (4) openness in research administrative policy]

Professor Ruggles convened the meeting at 1:15 and welcomed the new members of the Committee, Professor Bearinger and Mr. Klaas.

1. Graduate Fellowships

Professor Ruggles now welcomed Dean Dubrow to the meeting to provide an update on graduate fellowships. Dr. Dubrow distributed a handout with details on Graduate School fellowship funds and discussed three key developments in Graduate School policy related to student support, including raising the level of graduate school fellowships to \$21,000; awarding more two year fellowships; and rewarding units that develop multi-year funding packages for all of their students. She also provided facts related to Graduate School investments in the support of graduate students and shared news of new investments by the Provost in graduate student support.

Dean Dubrow reviewed the current status of the fellowship funds.

- 2005-06: 130 fellows (58 Graduate School Fellows and 72 Doctoral Dissertation Fellows)
(Graduate School funds are supplemented by one-time TCF funds)

* These minutes reflect discussion and debate at a meeting of a committee of the University of Minnesota Senate; none of the comments, conclusions, or actions reported in these minutes represents the views of, nor are they binding on, the Senate, the Administration, or the Board of Regents.

- 2005-06 costs: \$30,000 per fellow (stipend = \$17,500, health insurance = \$2,700, tuition plus U fee = \$9,700)
- Recurring fellowship budget (\$5.7 million) plus new funds (\$3.2 million):
 - GSF/DDF: \$3.3 million current plus \$1.28 million new = \$4.58 million
 - Block grants: \$2.4 million current plus \$1.92 million new = \$4.32 million
 - An additional \$300,000 is designated for DOVE fellowships
- Current year block fellowship accounts, which are decentralized to programs, are being increased by 30% immediately, for spring 2006 use or to carry over in FY 2007.
- 2006-07 fellowship cost estimates: health insurance = \$2,800, tuition plus U fee = \$10,200, for a total of \$13,000 in non-stipend costs.
- 2006-07 fellowship stipend costs @ \$21,000 plus \$13,000 in non-stipend costs for a total of \$34,000 per fellow. \$4.58 million divided by \$34,000 equals ~135 fellows.
- Beginning in 2006-07, many more Graduate School Fellowships (for incoming students) will be offered as two-year awards, which recipients may take in their second, third, or fourth year (which will effectively reduce the number of awards in out years).
- An additional \$1.5 million is to be allocated in FY07. If in the same proportion as the new \$3.5 million, \$550,000 in additional funds would increase the number of GSF/DDF awards by another 15, to 150+ fellows. OR, additional funds may be targeted to summer research awards of \$4,000 (subject to recommendation of the fellowship committee).

The effects of the large budget increase will be less dramatic than at first glance because 1) the larger share of the new funds has been designated as Block Grant fellowships, 2) necessary stipend increases, along with tuition/health insurance increases, will raise fellowship costs for 2006-07, and 3) the 2005-06 fellow numbers are higher because of the availability of non-recurring TCF funds.

Committee members and Dean Dubrow exchanged views on several matters, after which Professor Ruggles thanked Dean Dubrow for her report.

2. Update from the Office of Regulatory Affairs

Professor Ruggles next invited Assistant Vice President Bianco to provide an update from his office.

Mr. Bianco began by saying that his office is not well known, by design; it works in the background. It was formed by Senior Vice President Cerra in the mid-1990s in response to the University's troubles with NIH; Regulatory Affairs is now part of the Office of the Vice President for Research. He handles the operational side of compliance matters; Mr. Schumacher oversees the processes. Mr. Schumacher said that if individuals have questions about what they are doing, they should call Mr. Bianco's office.

Part of his job is to sign the form for the federal government ensuring the University is complying with regulations relating to subjects protection (human and animal). He is involved in policy development; a number of policies were revised last year. The University is the first to have a comprehensive institutional conflict-of-interest policy, which is still being implemented.

The Office of Regulatory Affairs has four divisions and seven FTE employees. The divisions are (1) conflict of interest (including managing the policy for the entire university and provides staff support for the two personal conflict-of-interest management committees), (2) clinical monitoring (of IRB-approved protocols for both the University and Fairview), (3) veterinary monitoring (for animal-approved protocols), and (4) general research policy and education. With respect to the last, they are working on revising the outside consulting policy and will bring it to the Committee soon.

3. Institutional Review Board (IRB) Issues

Mr. Bianco introduced a number of individuals involved with the IRB: Moira Keane, Director of the Research Subjects Protection Program (the administrative home for the IRB and IACUC), Carol Siegel, the Associate Director, and three of the IRB committee chairs: Professors Sue Berry (the executive IRB committee), Michael Oakes (the social and behavioral science panels for student research), and Sarah Jane Schwarzenberg (one of the medical panels). They have no special report, he said, but were present at the meeting to answer questions.

Professor Berry explained the structure of the IRB and how it relates to the institution. It is a peculiar committee, she said, because it is peer-constituted but mandated by federal policy and also includes non-institutional members. It is peculiar but it makes sense, she said. They do what the federal government mandates so they have sufficient representation from special areas (pediatrics, geriatrics), and if they do not have the expertise they need, they seek it. It is a faculty group but it is accountable directly to the Regents; their job is to protect human subjects so conventional governance processes do not apply, and the federal government mandates that the IRB be independent. The vast majority of its members, however, are faculty colleagues at the University, fellow faculty members who are also users of the IRB. She herself must obtain IRB approval for her research, Professor Berry pointed out. There are seven panels, six of which are working panels (four in medical fields, two in social sciences, and one of the latter is for student research because it includes special training activities—it assists students to do research without delays).

Professor Schwarzenberg made a plea that people volunteer to serve on the IRB.

Professor Oakes observed that the social and behavioral sciences panel is more contentious for faculty. One reason is that the rules were written by and for biomedical research, which created problems from the outset. In some institutions, there is no social science representation on the IRB, but that is not true here; the social and behavioral sciences IRB panel is filled with social scientists.

Professor Berry said that IRBs exist to protect human subjects. They (1) WANT research to be carried out, and they also protect investigators, (2) questions have been raised and suggestions made about streamlining the process, which the IRB endorses, (3) there is no reason not to make the membership lists of the IRB panels public, although they do not want to see individual members of the panels harassed, and (4) there is an appropriate concern that the PI does not always agree with what the IRB suggests and there has been a suggestion for an appeal process. With respect to the last, federal IRB

regulations leave no room for an appeal process but the IRB agrees there should be discussion and welcomes an ongoing dialogue. They work hard to accommodate PIs, she said, but one must remember that there is no RIGHT to do human subjects research, a privilege that the individual retains by following federal regulations. Ms. Keane commented that they will make more transparent the process a PI can use if he or she disagrees with the IRB. She also said that they will make public the names of the panel members in order to honor their volunteer contributions.

Professor Oakes said that they have ongoing discussions with PIs—the IRB makes suggestions, which the PI accepts or makes alternative suggestions in response. The process usually works out, and the appeal is within the regular channels of communication in the IRB. Professor Johnson said that a faculty member would have little idea if there is disagreement within the IRB about a specific proposal. Professor Berry said the panels have a general discussion after the PI presents the risks; the panel can decide it needs more information and there can be strong disagreements. They vote on all proposals and strive for consensus. There have been minority opinions (e.g., this research should not take place). Professor Schwarzenberg reported that her panels usually reach consensus, with only one or two people raising questions. Professor Johnson asked if information is available to the PI; are there minutes? Ms. Keane said that minutes are kept but only the decision is communicated to the PI; it would be unusual for a minority opinion to be communicated to the PI. And there are no names, Professor Oakes added; it is the committee speaking. Committee members must feel free to discuss proposals with the understanding that their comments are confidential, Professor Berry said; where they have strong dissent, they seek outside expertise, Professor Schwarzenberg added. Ms. Keane noted that applications to the IRB typically go through a department, or scientific groups will look at them, so by the time they reach the IRB they are about ready to go. Proposals that have had intense scientific review are usually in great shape, Professor Schwarzenberg agreed; where they have more problems is with unfunded, un-reviewed, single-investigator proposals. In the latter cases, the IRB has to start from the beginning.

Professor Oakes said they up the special student panel because typically there is no benefit to humanity from student research. These are usually learning projects, so they use three factors to evaluate proposals: risk, benefit, and training. The risk is usually low, there is usually no benefit, but the training is great. In the case of applications from someone with an advisor, they try to work with the advisor to enhance the training experience and get the advisor in a mentoring relationship with respect to human-subjects research.

Ms. Witson said she works with the IRB on a daily basis and commended the performance of the staff and panels. She offered suggestions on speeding up the process in order to meet deadlines and consolidation of responses when several different committees are involved. Ms. Siegel said that she is the ex officio liaison with PRDU (the Protocol Review and Data Use Committee that reviews protocols in the Department of Surgery for scientific and resource issues). The IRB has negotiated with the PRDU to not make stipulations to the consent forms. If they see something they believe the IRB missed, they call her and she adjudicates through the IRB, thus eliminating stipulations from multiple committees. Ms. Keane agreed that sometimes the process takes longer than they like and there are tensions because of the volume of proposals. The University has indicated there will be more money available, and they are trying to do more electronically, but there is a limit to how far that can go. They try to get information to the PI as soon as possible. Ms. Siegel added that every letter from the IRB must be written and then someone else must review it. She did not believe they are missing the 10-day deadlines, but they will try to get better. The problem is not electronics, it is lack of people, Mr. Bianco explained. And nothing puts

off a researcher more than a rude letter. Professor Berry agreed and said they work with people to help them understand the collegial process.

Mr. Bianco told the Committee that a big part of what they do is recruit people and work with departments that have a large number of projects but no representation on the IRB panels. Professor Schwarzenberg, he recalled, was a disgruntled researcher before becoming involved with the IRB. If someone does human subjects research, Professor Berry asserted, they have an obligation to participate in the IRB—and they will do better research once they have served.

Professor Ruggles asked whether an appeal could be made to another panel, if a PI has a dispute with one panel. Professor Berry said they try to have panels develop expertise and they do not believe faculty should "shop" IRB panels. They do occasionally have another panel review a project, but there have been no major differences. But there are cases with a minority opinion, Professor Ruggles said; there is no point to an appeal if there is a consensus on the panel, but if it is a close call, an appeal might make sense. The panel can work through a difficult case, Professor Berry said, and the executive panel that she chairs can help (they do not discuss individual cases but can help with the "what should we do about this" questions). They also help maintain uniformity in results. Professor Schwarzenberg said they will not ask one panel to second-guess another. There is no ultimate Supreme Court, Professor Oakes commented. The panel will engage the faculty member with a problem, Mr. Bianco said, but he is not authorized to override a panel decision—nor is the President or the Provost. If there is a problem, the PI is welcome to come back and discuss it, but by law there is no appeal. But there is more informal discussion and appeal than might appear to be the case, Professor Oakes said.

4. Openness in Research Administrative Policy

The Committee briefly discussed the administrative policy on openness in research, and agreed that it should bring the policy back to the full Faculty Senate. Gary Balas, chair of the Subcommittee on Research Openness, will present the policy to the Faculty Senate at the March 2 Senate meeting.

Professor Ruggles adjourned the meeting at 3:00.

-- Gary Engstrand

University of Minnesota