

Minutes*

**Senate Research Committee
Monday, December 9, 2002
1:15 - 3:00
238A Morrill Hall**

- Present: Gary Balas (chair), Sharon Danes, Sabine Fritz, Yev Garif, David Hamilton, Katherine Klink, Phillip Larsen, Sharon Neet, James Orf, Mark Paller, Virginia Seybold, Thomas Schumacher, Barbara VanDrasek
- Absent: Melissa Anderson, Gerry Baldrige, Victor Bloomfield, Kathleen Conklin, James Cotter, Kris Davidson, Robin Dittman, Lawrence Jacobs, Paul Johnson, Wendy Pradt Lougee, James Luby, Scott McConnell, Mehul Vora
- Guests: Senior Vice President Frank Cerra (Academic Health Center); Professor Patrick Brezonik, Carolyn Chalmers, Professor Amos Deinard, Jan Morse, Peggy Sundermeyer (research grant conflict resolution); Mark Bohnhorst (Office of the General Counsel); Edward Wink, Sheryl Goldberg (Sponsored Projects Administration)
- Other: none

[In these minutes: (1) Regents' policy on HIPAA (Health Insurance Portability and Accountability Act) regulations and impact of the regulations on the University; (2) University stance toward start-up companies initiated by University faculty and staff; (3) structure of the Office of the Vice President for Research and of the Dean of the Graduate School; (4) dispute resolution in research]

1. Health Insurance Portability and Accountability Act (HIPAA)

Professor Balas convened the meeting at 1:30 and welcomed Senior Vice President Cerra and Interim Vice President Hamilton to discuss the HIPAA policy. HIPAA is federal law.

Dr. Cerra said he welcomed the opportunity to talk about this "interesting and challenging" topic. The subject at this meeting is the policy being proposed to the Board of Regents, which will be taken to the Regents for information this week and action in February. The policy provides that the University will be in compliance with the privacy requirements for personal health information data as expressed in existing law and regulation, including HIPAA. The policy also delegates to the President the authority to administer the policy and adopt necessary procedures. The law requires the institution to adopt a policy, Mr. Schumacher pointed out; the University has no choice.

Behind the policy (which is four paragraphs) lies a very thick evolving University, non-regental, administrative policy, Dr. Cerra told the Committee. The procedures are kept out of the Regents' policy so that it can change as the regulatory rules change or as court cases alter the regulations. The policy does call for reviewing the administrative policies and procedures every five years. He confirmed that the

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policy and procedures will be reviewed AT LEAST every five years--and the procedures probably more often as the regulatory environment changes. He agreed that the words "at least" should be inserted in the policy.

Will this policy align with the state's proposal about medical records? That is for the state's attorneys to decide, Dr. Cerra said. He guessed that the matters could end up in court unless the legislature re-interprets the law, because the state proposal calls for including names and other identifiers that are not permitted by HIPAA. The University will be in compliance with HIPAA, he said; what is important is that the University is in compliance with state and federal laws as they exist today.

Why is there need for a specific HIPAA policy, Dr. Paller asked? The University has a policy that says it will follow applicable state and federal laws. He said he could understand the need for the implementing procedures, but why a separate policy? It is the interpretation of the administration that the federal government wants to see a POLICY, Dr. Cerra said; pragmatically, the General Counsel's office has advised that the law requires a specific policy and that the University therefore should adopt one in order to have an effective compliance policy.

Dr. Larsen said he has heard that one should not underestimate the impact of HIPAA on research on health issues and how the University deals with the health of its employees and students. Dr. Cerra said there are three major parts to the impact of HIPAA: one, on anyone with access to personal health information, including institutions; two, on health care providers; and three, on research. The procedures are VERY complex, roles and responsibilities are still evolving, and the education plan is being developed. This Committee will be informed about these efforts. The research part of the policy/procedures is a different set of regulations and set limits on what kind of personal health information is available for research purposes. As always, all research involving humans requires review, approval and oversight of the Institutional Review Board.

Who will implement the training, Dr. Larsen asked? There is a University-wide team looking at that, Dr. Cerra said. Some will be provided through central processes, some by privacy coordinators in the units, and some will be available on line.

If there is non-compliance, the issue could end up at the Board of Regents, Professor Orf commented, since this is a Regents' policy. That is correct, Dr. Cerra said; the rest of the University will help comply. The provisions go beyond that, however, because if one violates the policy as an individual, there are individual penalties. The Board has institutional responsibility.

The Committee unanimously endorsed the proposed policy, with the caveat that the words "at least" will be inserted where the policy calls for a review every five years.

2. Start-Up Companies

Professor Balas next asked Interim Vice President Hamilton to talk about the University's stance toward start-up companies launched by University faculty and staff.

Dr. Hamilton said it is important that the institution think about this issue and the Committee has asked questions about it. Patents and Technology Marketing (PTM) has been holding educational meetings around the campuses for the last several years on how to start a business and the variables that

must be dealt with. He said he has been paying attention to this issue the last four or five months and has reached conclusions about what must be done.

-- The educational efforts of PTM will continue, although the form may change; they should be more educational (PTM has done an excellent job thus far).

-- The University needs to develop a start-up one-stop, sponsored jointly by PTM and the Vice President for Research. In talking to people outside the University, he has learned that business is interested in funding start-ups but often the cart gets before the horse: the company starts before it has a business plan, legal work done, and a management team in place. This sequence of events leads to chaos. The biggest mistake that faculty make is that they want to run their own business. Venture capitalist funds look very carefully at who is running a company--who the CEO and CFO are--and unless they are comfortable with the individuals in those positions, attracting venture capital can be very difficult.

Dr. Hamilton said he wants faculty to be able to get all the information they need at a one-stop--and it will not cost them a penny. There are enough people in the community who are willing to work pro bono and help so that faculty can get their efforts off to the right start. He said he realized that Professor Klink has expressed concern that faculty are or may be forced into doing start-up companies; that is certainly not the view of central administration, he said, but he knows that some departments are anxious to get start-up companies going if they believe they have something that has commercial value. But if a faculty member or department has an idea and wants to learn if a start-up company could succeed, the administration wants to help them. Dr. Hamilton later added that he would like to see a partnership with the Carlson School in offering these services because the CSOM faculty has a great deal of expertise to bring to the start-up efforts.

PTM has two mechanisms to vet start-up company proposals. One consists of a committee of business people in the community that meets once per month and evaluate proposals; all of these people are very successful and very candid about chances because they know that of every 100 start-up companies, only one or two will succeed. A second is the recently-established Business Commercialization Advisory Board, which consists of 25 leading business people in the state and which offers help to faculty who want to start a business--it offers essentially a buddy or mentoring system. There is a lot of enthusiasm among the participants; a number of them are retired business people who want to help. This group is still in the early stages.

Professor Seybold asked where conflict of interest considerations fit in to start-up companies and whether faculty are advised how to help resolve a conflict of interest. Dr. Hamilton replied that PTM educational efforts include conflict of interest. This is a significant issue, he agreed, and faculty will be helped in resolving potential conflicts; management plans will be taken to the deans and the Conflict Resolution Committees.

Dr. Larsen inquired about the one-stop and the office to support it. Dr. Hamilton said they have someone working on it, someone who knows just about all the venture capitalists in the state, it seems, and that person will have an assistant to help the faculty. This is not something a lot of people will use, he pointed out, but the office will assist in finding volunteer help in the community. These start-ups are most often conceived of as bio-tech companies but there are other incubators that can be supported as well. The University is a johnny-come-lately to this effort, Dr. Hamilton noted; other universities have

been involved in helping start-up companies for some time. The discussion has been going on here for a long time; he said he would like problems to be resolved so the University can get these incubators going.

Would this service be available for students as well, Professor Neet asked? Dr. Hamilton said he found it difficult to identify what a graduate student would be able to spin off into a company. Silicone Valley and the area around MIT are full of people who dropped out of college, did not finish their programs, and started companies, Professor Neet observed. Often the true entrepreneurs do not obtain degrees. Dr. Hamilton agreed that is the way spin-offs often occur--people leave a university but want to maintain a close relationship with the faculty. He said the University needs to think about those who leave--who often do not follow a recipe in developing companies--and how it might help them.

Dr. Hamilton said that the one-stop and services to assist with start-ups would also be available to staff.

What are the benefits to those who provide pro bono help to people with start-ups, Dr. Van Drasek asked? If one helps a start-up get going for free, Dr. Hamilton said, it is expected that the company will use one's firm later. It is the relationship that is important.

The University embraces start-ups but also washes its hands of them, Professor Balas said. It does not give an endorsement but a newsletter from the Office of the Vice President for Research talked about three such companies--it describes them and gives recognition to them. Dr. Hamilton said the University is proud of companies that are spun off from its work and will talk about them even though the University has no relationship with them. Faculty members may still be involved with them.

Professor Orf asked if there had been any thought recently about a quasi-relationship between the University and a start-up company. Dr. Hamilton said there has not; there are many problems with such relationships. Dr. Paller asked if there has been any change in the University's position to suggest a greater role in establishing start-ups extending beyond matching start-ups with funding sources. Dr. Hamilton said the University must be divorced from any greater role. There is an organization (Sota Tec) company that helps with start-ups, such as obtaining funding to complete a research program. The University would like to keep its relationship with Sota Tec; it is a natural way for the University to be involved.

There is no institutional policy on departments granting leaves of absence to faculty to start up a company, Professor Balas asked? Is it department by department? This is a department management issue, Dr. Hamilton said--if the business of the department can be managed while the faculty member is on leave, that is up to it. If the University grants a leave, Mr. Wink said, there is a limit to its length and there must be value to the University. Some departments are more willing, some are not, Professor Balas said. Mr. Wink agreed; they must see a value to the leave. And filling a vacancy may be difficult, Dr. Hamilton pointed out. So one must have support from one's department, Professor Balas concluded; is the institutional stance likely to change, he asked? It is not, Dr. Hamilton said.

Professor Balas said he has looked at what other universities do. Stanford has funds to help faculty take ideas to the next level. Dr. Hamilton said he is trying to identify funds to help faculty finish research and move forward on an idea that may have commercial potential; the University would provide seed money to complete the work at the University. He has not yet identified the funds.

Professor Balas thanked Dr. Hamilton for his report.

3. Organization of the Vice President for Research and Dean of the Graduate School Offices

Professor Balas drew the attention of Committee members to the organizational chart for the Vice President for Research and the Dean of the Graduate School offices and to the draft statement that he had prepared for the Committee to consider sending to the Faculty Consultative Committee. Committee members made a few comments about the organizational chart.

Committee members expressed concern that if the two positions are again joined in one person, the work of the Dean of the Graduate School will take second place to that of the Vice President for Research, particularly as the demands on the VP office continue to increase. The Committee agreed it wished to state more clearly its concerns along this line: the Graduate School is very important and the University must have someone with the authority and resources to get the job done.

The two offices have not been separated very long, Professor Neet observed; what does Dr. Hamilton think? Dr. Hamilton pointed out that he is biased on the matter but said that given the duties of the Vice President for Research, he could not find an hour per week to be Dean of the Graduate School. That is not the way the Graduate School should be run, he said; both of these jobs are huge. He said he believes that the two positions should remain split, although acknowledged that others may have a different view. The reservations expressed by those who prefer the positions be merged arises from the perception that the Dean of the Graduate School would not have the same voice in central administration that he or she would if the position were joined with the Vice President for Research. He personally said he did not believe that would be true.

Dr. Larsen agreed; he urged that the Committee support keeping the two positions separate and giving the Dean higher visibility. Dr. Van Drasek commented that ideally one would have a 400%-time person; since that is not possible, the Dean should continue to be Vice Provost for Research as well as Dean. Dean Bloomfield, by being Vice Provost, sits on the Executive Vice President and Provost's Executive Council, Dr. Hamilton pointed out, which no other dean does, so the Dean of the Graduate School is already in a different position.

(After dealing with the next agenda item, below, the Committee returned to this one at the end of its meeting.) The Committee discussed which groups the Dean would sit on by virtue of being Vice Provost for Research; it would be the Executive Vice President's administrative group, not that of the President (on which the Vice President for Research sits). The Dean would report to the Executive Vice President and Provost twice, both as dean and as vice provost. The idea behind the Committee statement, Dr. Paller commented, appears to be that the Dean should participate in meetings that he or she would not otherwise be in as a dean.

The real concern is that the Graduate School not be neglected if the positions are split and that it will receive the attention it should have. Professor Balas agreed to redraft the statement to reflect the views of the Committee.

4. Research Grant Conflict Resolution

Professor Balas now welcomed Carolyn Chalmers (University Grievance Officer), and Amos Deinard, Jan Morse (Student Dispute Resolution Center) to discuss dispute resolution during the conduct of research.

Ms. Morse began by telling the Committee that she and her two colleagues work with members of the University community to resolve conflicts that can be academic or employment-related. They also see opportunities for problem prevention and ways the University can do a better job of dealing with problems. Last fall at a conference there was mention of a program whereby people sign off on partnership agreements; they decided they did not want anything quite so formal but they do want people to know about the offices they represent and that they can help to resolve conflicts.

Ms. Chalmers distributed copies of a handout with three items: a draft letter to Principal Investigators transmitting a list of things to do to anticipate and avoid disputes during research and offering the services of their offices in helping. Use of the service would be strictly voluntary. The list of topics reflects their experience and that of others in handling issues of coordination and management as well as dealing with problems when a research project succeeds beyond expectations or when it falters. The list does not try to answer questions, because each project is highly individual, but many projects can benefit from thinking about the issues it raises.

Professor Deinard said that in many years of dealing with the Judicial Committee and research ethics questions in the Office of the Executive Vice President and Provost, he has been surprised at the number of times people who have been friends become enemies. As a pediatrician, he believes in primary prevention. The services, he repeated, are all volunteer; they provide help getting through rough spots, if a PI wants it, and they can become involved either before or after a conflict arises.

The Committee discussed the letter and the list for some while and made several points.

- The "strictly voluntary" part of the service removes any pressure. The letter to the PI should come from the college research associate dean, although it may be that a central office should have the responsibility of reminding them to do so each year.
- The letter should be sent to as many people as possible who are involved in a research project, not just the PI.
- This information should be sent to PIs, perhaps by the Vice President for Research office, before a research project begins, and not just posted on a web site. The deans can also promote it. There really needs to be a publicity campaign.
- The same information should be made available to those who engage in non-funded research; the same issues can arise.
- The issues can be highlighted in Responsible Conduct of Research training programs. The only drawback is that RCR training is a one-time event; there is no program of continuing education yet. It may be that reminders or training should be required whenever a grant is received, or once per year, whichever is less. People do forget.

- The issues list should point out that there are University policies on some of these subjects. There needs to be a place identified where people who have questions can go for answers; they should ask the questions and get answers, not guess. Mr. Schumacher's office should be the one listed (Mr. Schumacher said that is acceptable as long as he does not have to respond to questions right now because his office is not staffed to do so--but he will be able to do so in the near future).
- Big issues that should be on the list are how to deal with grant funding that is less than what was sought and how to deal with budget cuts.
- a bullet should be included regarding assuring clear understanding of the responsibilities for preserving confidentiality of confidential sponsor information, and re any restrictions on access to that information by research group members.
- Especially with a large or complex research lab, it might be helpful for the PI to discuss with the research group who is authorized by the PI to initiate purchases under the grant--a lab manager, for example--and the process that will be used to assure that the proper charges are put on the proper grants.

It was agreed that revisions to the letter and the list of items, once they have been reviewed by the college research associate deans, would be brought back for a final review by the Committee.

Professor Balas thanked the group for presenting the proposal to the Committee.

Professor Balas, after the conclusion of the discussion about the structure of the Vice President and Dean offices, adjourned the meeting at 3:10.

-- Gary Engstrand

University of Minnesota