Minutes[*]

Senate Research Committee
Monday, January 26, 2004
1:15 - 3:00
238A Morrill Hall

Present: Gary Balas (chair), Dianne Bartels, (Shirley Nelson Garner for) Victor Bloomfield, Christopher Cramer, Dan Dahlberg, Sharon Danes, Robin Dittman, Kathy Ensrud, Steven Gantt, David Hamilton, Michael Hughey, James Luby, James Orf, Thomas Schumacher, Maria Sera, Charles Spetland, George Trachte, Barbara VanDrasek, Jean Witson

Absent: Darryn Beckstrom, Kathleen Conklin, James Cotter, Paul Johnson, Katherine Klink, Andrew Koch, Phillip Larsen, Mark Paller, Virginia Seybold, Michael Volna

Guests: Winnifred Schumi (Oversight Analysis and Reporting), Ed Wink (Sponsored Projects Administration); Greg Brown (Office of the General Counsel)

[In these minutes: (1) Mt. Graham telescope project; (2) report on faculty compliance focus group discussions; (3) policy on use of royalty income for technology commercialization]

1. Mt. Graham Telescope Project

Professor Balas convened the meeting at 1:15 and explained that at the next meeting he has invited several groups to talk about Mt. Graham. The Faculty Consultative Committee wants something from this Committee and the Committee on Social Concerns about the resolution introduced at the last Senate meeting. He has asked representatives from the American Indian Studies Department, the Physics Department, and the Social Concerns Committee; after the discussion, this Committee must decide if it concurs with the Social Concerns Committee resolution, wants to draft a joint resolution with it, wants to reaffirm its previous statement, or adopt a new statement. He asked Committee members to let him know if they wished to draft a resolution.

2. Faculty Compliance Focus Groups

Professor Balas now asked Mr. Schumacher to review the findings of the focus group discussions with faculty about compliance issues.

Mr. Schumacher related that when he started in his position he created a committee, the Research Compliance Committee, comprised of representatives from the offices that support research. The committee is to address issues of the culture of compliance and how to improve it. One of the ideas they came up with was a self-assessment; one way to do that was through a series of focus groups. They had four such discussions. Mr. Schumacher cautioned that this was not a scientific study or a representative sample; they prepared a list of questions and had 19 faculty participants in the four sessions.

[*] 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. Schumacher distributed a summary of the results of the focus group discussions and identified several themes that emerged.

The first was transparency and service: there is need for a faster turnaround on materials and improved communication (where in the queue are their activities?). The information communicated to researchers needs to be accurate and timely. Researchers want to know the source of the regulations they are being asked to comply with. There is a sense that there is a culture of distrust from the staff that researchers need to deal with. Researchers are concerned about the consistency of the responses they receive to questions; sometimes, it seems, the answer depends on who one talks to.

A second theme was learning from trial and error and tolerating violations. Researchers learn about regulations through an audit or other non-systematic ways. They also gave examples of working around the rules rather than trying to follow them.

A third theme was institutional knowledge: the way researchers obtain information. They use experienced colleagues, find out what worked in the department, and rely on informal networks.

A fourth theme was delegation of responsibility. A number of researchers said they leave compliance matters to staff to whom they have delegated the responsibility, especially in accounting.

There were also a number of positive comments about administrative support for research (e.g., web sites, IRB, IACUC, Environmental Health and Safety.

Mr. Schumacher said he was intrigued and concerned about the interest in the source of the regulations. It is necessary to help people understand that University policies are designed to implement legal regulations; they have tried to integrate these requirements so there are not separate forms. The University creates hoops only because they are established in federal regulations. The policies are intended to help the University comply with federal law.

In terms of trial and error learning, that is not all bad; people do learn through audits. His concern, Mr. Schumacher said, is that faculty do not appreciate how the government will view certifications. If someone signs a form saying they have personal knowledge or attesting that something is true, the government will hold that person to the statement. Trial and error learning is acceptable in some circumstances that do not relate to legal obligations, but people must understand what the government expects where it requires certification.

On the issue of delegating authority, that is the way work gets done and it is appropriate to delegate responsibilities to support staff. Delegation is not abdication--researchers must be sure that the people to whom they delegate tasks have the necessary time and skills and be sure that there is oversight. If there is an incident, the government will want to know what happened and will not care who did it.

There is a perception of inconsistency in answers that researchers receive to questions. That can be a result of the skill set of the people answering the telephone; it may also be the case that the person answering the question does not always get the full story--and the answer changes when more information becomes available. Mr. Schumacher said he did not know if there is a problem or if answers depend on the messengers.

With respect to attitude, it may be that some people do not understand the roles that various offices play. The IRB, for example, is not a partner in research; it is charged to protect research subjects. The institution is helped if the IRB asks tough questions. (Mr. Schumacher said he was making no statement about how good a job the IRB is doing--that was outside the scope of the assessment.)

Mr. Schumacher said he found it a good sign that the focus group participants were worried about doing what the rules require. He also said he was pleased that this Committee and the Vice President for Research wanted to pursue this self-assessment. He asked if there were questions.

Professor Balas said he was in the group that wanted to know whether a requirement was a University or a federal policy. The University makes hoops to meet federal policy that are not suitable for each group (e.g., travel reimbursement, telephone calls home when traveling). It is frustrating when one does not know the source of the rules and when one learns that colleges interpret them differently. What can the administration do to address this problem, Mr. Schumacher asked. Let researchers know if something is a University policy and what federal policy it is tied to. For example, if the policy is based on an NIH regulation, that may not be a good match for someone in the arts; the University needs to be flexible.

In terms of signing off on documents, Professor Balas continued, principal investigators have a lot of responsibility but they are also unable to affect some University processes. He said he could do nothing about signing a contract, paying people, getting subcontractors, and so on. Mr. Schumacher said he just wants to be sure that people understand how the government treats certification. If you say you know something, and you really don't, you expose yourself to liability if there is an investigation. If you rely on reasonable information, however, that is fine. Faculty must appreciate, however, that they have risk if they sign something that says they have personal knowledge about something when they in fact do not.

Most policies refer to the federal policies they are trying to respond to, Dr. Hamilton said. There are local variations in the interpretation of policies; there is nothing that says CBS cannot interpret a policy differently from IT. The only restriction is that a unit may not interpret a policy more liberally. He suggested that Professor Konstan make a presentation about the Federal Demonstration Partnership because this is a big issue at the federal level. They are finding that institutions enact policies that are more stringent than federal regulations in order to avoid having the federal government investigating them. He said he believed the University should make its policies as flexible as possible, except that they cannot violate federal regulations. Mr. Wink explained that any discretion in policy interpretation must be applied consistently within the unit. Federal agencies rely on institutions to have good policies because they know there is less risk of inappropriate use of federal funds in those institutions that have good policies.

It is also not possible for an institution to say that if it is an NIH policy, it will do things one way, but if it is another agency regulation, it will do things another way, Ms. Schumi told the Committee. Is there a way to understand which organization has the most stringent policy, Professor Orf asked? One might discover that something that makes no sense in some case is because the policy came out of the Department of Defense, for example. DOD, NSF, and so on have different requirements. Dr. Hamilton agreed and said that they have a spent a lot of time working with federal agencies to bring the University's conflict of interest policy to a coherent state, because the agencies all interpret it differently. When NSF came to the University to hear about procedures at the federal level, what they heard about was consistency. But the federal agencies have many different and inconsistent policies. Is there an attempt to get consistency across agencies, Professor Orf asked? The Federal Demonstration Partnership is speaking loudly on this issue, Dr. Hamilton said.

What was the motivation for the faculty groups--being proactive or a response to faculty grumping, Professor Dahlberg asked? They were interested in proactive efforts, Mr. Schumacher said. Dr. Hamilton commended Mr. Schumacher for undertaking the assessment; he said he was taking the results very seriously and believed them very important.

Dr. Hamilton distributed another handout entitled eResearch Central. This is a result of a plea from Professor Balas and something that his office has been working on even before he became Interim Vice President. eResearch Central is intended to eliminate the need for researchers to go from place to place for compliance information. The first release will be this spring and it will make available a great deal to researchers: initiating actions, forms, review of current work, tracking, and so on. It will not be tied in with the financial system but they will establish links, Ms. Schumi said.

Dr. Hamilton reviewed the elements that will be in eResearch Central. Ms. Schumi promised that the acronyms will be explained in the version that is finally rolled out.

Professor Bartels reported that she could not find HIPAA and RCR courses on the web; it took half an hour to find what she needed. And the two are not on the same system. That is the way they were designed, Dr. Hamilton said. RCR materials were designed a long time ago and have their own database; HIPAA is in the Academic Health Center on WebCT. They will bring them together, he said; that is part of the thrust the next few months. There is, for example, a database on radiation on a PC--that is not secure. All of these databases need also to be brought to a standard of security as well as ease of use. eResearch Central will not answer all of the questions raised in the focus groups but it is a start, Dr. Hamilton said, and they will continue to work on the issues. One meeting he was involved in led to the suggestion that it might be a good idea to have a Vice President for Research help line, with a live person on the line who can route calls and check whether questions were answered. The cost would not be inconsequential but might be justified in terms of reduced frustration.

Professor Balas thanked Mr. Schumacher for his presentation.

3. Policy on the Use of Royalty Income to Support Technology Commercialization

Professor Balas turned to Vice President Hamilton to lead the discussion; he, in turn, called on Mr. Brown from the General Counsel's office. The draft Regents' policy on the use of royalty income to support technology commercialization read as follows:

> This policy governs the provision of financial support by the University of Minnesota (University) to non-University entities to encourage, promote, and assist in the commercialization of patents, copyrights, and other intellectual property (*University technology*) created by University faculty, staff, and others and owned by the University.
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> Subd. 1. Definition. "University technology" shall mean patentable inventions, copyrightable works, and all other forms of intellectual property created by University faculty, staff, and others and owned by the University in accordance with other Board of Regents (Board) policies.

Subd. 2. Guiding Principles. The following principles shall guide the commitment of financial support to non-University entities under this policy:

(a) Relationship to University's Mission. The commercialization of University technology is consistent with the University's mission of research and discovery, teaching and learning, and outreach and public service. Financial support provided to non-University entities shall directly encourage, promote, or assist in such commercialization.

(b) Compliance. The commitment of financial support shall comply with all applicable laws, regulations, and rules.

(c) Eligible Recipients. Eligible recipients shall be tax-exempt, nonprofit corporations.

(d) Limitations on Financial Support. The source of financial support shall be royalty and other income the University earns from technology licensing. Such financial support must not impair or adversely affect the University's mission.

Subd. 3. Delegation of Authority. The president or delegate may commit the University to provide financial support of $250,000 or less, consistent with Board of Regents Policy: "Reservation and Delegation of Authority."

Subd. 4. Reporting. The president shall report to the Board each year on the commercialization of University technology, including an analysis of any financial support provided to non-University entities under this policy.

This continues a discussion began in December, Mr. Brown said, about the administration's ideas about commercialization; the University is interested in using royalty income to spur commercialization and in particular to support non-profit commercialization vehicles such as technology parks and incubators. The proposed policy had been provided to the Committee earlier; Mr. Brown said that implicit in the policy is the question about whether the University should be spending money on these endeavors. The administration believes it should. If the answer is yes, then under what conditions should it spend the money? The policy lays out those conditions by identifying the source of funds and the entities that should receive them. Section 2a, for example, requires that the support is tied to the University's mission.

In addition, Mr. Brown said, they have always talked about an advisory committee that would review what organizations should receive funds; the establishment of a committee is not in the policy but is something the President can do. The President has assured him he will appoint such a committee, Dr. Hamilton said.

What is left out of the policy is guidance on how to choose what to fund and what not to fund, Ms. Witson said. To be tied to the University's mission is very broad. The idea is not to impose too many strictures, Dr. Hamilton said; if the policy does so, and circumstances change, then the Board of Regents must make a change. This draft is itself somewhat more restrictive than some Board members may be comfortable with. They are trying to write a policy that is not just for one set of circumstances, Mr. Brown explained, because they are not sure what the future might bring. The advisory committee would have to articulate demonstrated objectives for those organizations to which it grants funds. For example, with respect to University Enterprise Laboratories (UEL, the biotech incubator which it is proposed would be the first to receive support from the University under the policy), the committee will have to think deeply about what the University will receive in return for the funds it would provide in support of UEL. Before any proposal goes to the Board of Regents, the committee must articulate what the University will get--and what it gets has to be tied to the mission, Mr. Brown said.

Professor Dahlberg said he has tried to figure out what kind of organization a not-for-profit company would be, but one that would turn a University patent into a money maker. UEL is an example, Mr. Brown said. The policy limits support to non-profits because it is not driven by financial return but by "mission return." If the University has an opportunity to put money in a for-profit company, that would be viewed as an investment opportunity. UEL is non-profit; the University would sign a lease and provide funds to pay for operations and building refurbishment. Who benefits, Professor Dahlberg asked? UEL, as the landlord for start-ups using University intellectual property, Mr. Brown said. They are for-profit companies, Professor Dahlberg said, so this is a way to give money to for-profit companies. Vice President Hamilton disagreed; it is a way to provide affordable space for for-profit companies. There is an ulterior motive, he agreed: The companies will be using University intellectual property using licenses issued by the University.

It does not say this in the policy, Professor Balas said. It is says tax-exempt, non-profit companies. The incubator might not rent to University-based companies. Mr. Brown clarified that all four of the conditions in Subd. 2 must be met before University financial support will be extended. (a) specifically provides that the entities must be tied to the University's mission.

Professor Orf asked about the makeup of the advisory committee. The President will appoint it and it will include both administrators and faculty, Dr. Hamilton said. And it will advise the President about any proposals made under the provisions of the policy? It will. It will not be able to veto proposals but it can suggest to the President whether or not support should be extended? That is correct, Dr. Hamilton said.

There is an additional reason to limit support to non-profits, Mr. Brown said. A non-profit organization can earn a "profit" but must use the money in the public interest. There are non-profits that are not tax-exempt; to receive University funds, an organization must be both non-profit and tax-exempt. The University is relying on the IRS vetting an organization for tax-exempt status to be sure it is congruent with a public mission.

Professor Luby inquired how sure the University would be that advisory committee members would not have a conflict of interest with the proposals? That is a very legitimate concern, Dr. Hamilton agreed, and would require careful attention. The University insists on avoiding a conflict of interest for any other investments, Professor Luby noted. Professor Balas said he understood that the President is committed to appointing a committee, but the policy can be used in different ways if a different president has other criteria. Mr. Brown pointed out that the University cannot spend more than $250,000 without express approval of the Regents (which is standard practice for the Board for all expenditures and merely triggers Board action; it does not affect review by the advisory committee, which will occur in all cases). For expenditures of less than $250,000, there is nothing inappropriate about the faculty saying the administration should create a policy on how the decisions will be made. But in the case of administrative policies, Professor Balas pointed out, all the administration has to do is notify the faculty that the policy is being changed. Dr. Hamilton inquired what he had to do to convince the Committee that President Bruininks is an honorable man. Professor Balas said the point was not about President Bruininks, it is other presidents in the future that one might be scared about. Professor Dahlberg agreed and said that things can evolve over time. Mr. Brown later added that while the Board of Regents will not see expenditures of less than $250,000 during the year, the Board does receive a year-end report, and will see items if they involved other Board policies (e.g., lease of land).

How royalty income can be spent is driven by the Bayh-Dole Act, Professor Balas observed. There are two conceptual uses for royalty income under Bayh-Dole, Mr. Brown said. One is support for commercialization, the other is support for research and teaching. If it turns out that a proposal to spend the royalty income is inappropriate under Bayh-Dole, it should not be supported.

Professor Sera said she did not like this policy and was against it. She maintained it is not with the University's mission and that the money could be invested in other ways inside the University. The University is not an expert on start-ups. The University does not need to be an expert on start-ups, Dr. Hamilton explained; the support will go for a building that will support start-ups. This is a subsidy the University is providing to companies, Professor Luby said. Professor Orf disagreed; he said the University is providing support for start-ups to ensure that they have a better chance of success. As the University licenses technologies, it is within the University's mission to help the start-ups with the licenses to succeed.

How does this not duplicate what small business development organizations do, Professor Danes asked? There are a number of such organizations throughout the state. Mr. Brown said that one concern about the policy is that one can get embroiled in discussion about particular applications of it. He agreed that if the private sector is already providing a service at a reasonable price, the University should not be doing it. But it is not, Dr. Hamilton said. There is a dearth of affordable wet lab space close to campus, Mr. Brown said; providing that space is what meets the needs of UEL. It might be that different needs would arise for other entities or other proposals. If there were such space close to the campus, the University would not support a proposal.

Inherent in the policy is the view that faculty do research at the University and there is a public benefit to getting it out, Ms. Witson said--that it is good public policy to get the research out. She said she did not have a problem with that idea. She said she was more worried that the tax-exempt, non-profit organization would make decisions about who benefits and if the proposal fits within the guidelines; the University will have no say in those decisions. That could be a very political process, with decisions to fund one kind of research and not another.

The University recognizes its lack of competence in picking start-up winners, Mr. Brown said. If, however, it gives a grant, it does not turn over the money to the non-profit without a covenant on what it can do (the provisions of the policy). In this way the University will provide a better chance of success without dictating what choices will be made. The University is not in the start-up business. Ms. Witson said that did not answer her concern; would it be possible to add language to the policy that decisions about who benefits from University funds will be under the guidance of a committee? Dr. Hamilton said there are ways of doing that other than through the Regents' policy. There will be a committee that will grapple with criteria, Mr. Brown said; they have included the language requiring that the recipients have a tie to the University's mission, but it is difficult to craft the language that is needed.

Professor Orf asked if the committee to be formed by the President would serve at the pleasure of the President or if it would be a permanent committee to implement the policy in the future, including after the current president is not in office. His bias, Dr. Hamilton said, is that it be an ongoing committee that pays attention to the policy, although the membership could change over time. How can that be assured, Professor Orf asked?

Professor Dahlberg said he would like to see a sunset clause in the policy in order to be sure that it would be reviewed at a certain time in the future. The sunset will come with the lack of funds, Mr. Brown said; this policy does not envision the University spending millions of dollars, year after year.

The reason there are licenses and patents and discoveries is because of research at the University, Professor Balas said. A better place to invest the money would be into places where research and technology is being developed before companies decide to put money into them. It would be better to spend the $2 million proposed for UEL inside the University instead. Dr. Hamilton recalled that he had been at a meeting at which he had projected University royalty income; they have made conservative projections about the Glaxo income because there may soon be better AIDS drugs on the market. The University at present receives about $34 million from that one license; the money goes to the inventor, the department/college, and the Vice President for Research office. His office has not spent all the money so it has accumulated, Dr. Hamilton reported; it goes into three pots. (1) The commercialization of intellectual property, consistent with Bayh-Dole, the Regents' mission statement, and the land-grant mission. (2) The 21st Century Fellowship Fund, which will eventually have $45 million that will generate $2 - 2.5 million in matching funds for graduate fellowships. (3) The research enterprise, in two ways. First, a 21st Century research endowment, which in seven years will be about $35 million, which will generate about $2 million annually for use however a group responsible for it sees fit; it will be an opportunistic investment pool with a faculty oversight committee so the University does not miss opportunities. Second, a small amount each that Dr. Maziar committed to biomedical research, for small grants and seed grants; the funds are run through the Graduate School. In addition, his office has provided funds for other things, such as $500,000 per year for four years for the libraries for on-line journal subscriptions and a small amount for burgeoning areas in the University that need infrastructure support (e.g., they have the equipment but not the necessary support for it). His office does a lot for research, Dr. Hamilton concluded, beyond the potential use of royalty funds for technology commercialization. Part of the need is to find a better mousetrap for intellectual property and this is one mechanism to do so. He said he wants to talk to the Committee and others about additional ideas he has. He said he hoped the Committee understood that this is an important element in the strategy to devise a mousetrap for the commercialization of intellectual property.

With respect to the University funds, Mr. Brown told the Committee, they have structured the policy so that if UEL cannot raise enough money to start, the University money goes in last. If a company does not raise the other money it promised, it will receive no money from the University. The University's money for UEL will be the last money in.

Professor Balas said that Vice President Hamilton has asked the Committee's opinion on the policy so it should vote. Mr. Brown said he has taken two messages from the discussion: that the language about all four conditions in Subd. 2 controlling should be clarified and that the advisory committee should be a permanent committee. Dr. Hamilton said the Regents would not accept a policy with a sunset clause in it, in response to a renewed suggestion from Professor Dahlberg. A policy can always be reviewed.

Professor Orf moved that the Committee support using royalty income for support of technology commercialization in concept. The Committee voted 9-2 in favor of the motion, with two abstentions. At Professor Dahlberg's suggestion, the Committee decided not to vote on the specific language of the draft policy. Dr. Hamilton agreed that any changes suggested by the Board of Regents, when the review the draft in February, would be brought back to the Committee. He said he would mention to the Board that there has been faculty consultation on the policy and that there has been unease about it.

Professor Balas adjourned the meeting at 2:50.

-- Gary Engstrand

University of Minnesota