

Senate Research Committee

Minutes of the Meeting April 27, 2015

[These notes 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 notes represent the views of, nor are they binding on, the Senate, the Administration or the Board of Regents.]

In these minutes: [Internal Sales Reports (ISOs) summary and status of recommendations; Psychiatry clinical trials case and University reforms; working with a 501(3) organization; capital planning and building expansion as it relates to research; Graduate School and preparation of postdocs; resolution on parental leaves]

PRESENT: Maria Gini, chair; Bill Arnold, Daniel Habchi, Philip Herold, James Orf, Brian Herman, Bob Lewis, Jeannette Gundel, Lisa Johnston, Sue Paulson, Michael Kyba Frances Lawrenz, Carol Carrier (for Al Levine), Scott McIvor, Mike Volna, Phil Zelazo, Nicole Victoria, Tommy Vaughan, Teresa Rose Hellicant, Elizabeth Steinert, Jayne Fulkerson, Hinh Ly, Michael Schmitt

REGRETS: LaDora Thompson, Seung-ho Joo

ABSENT: Brian Johnston, Tucker LeBien, Lynn Zentner, Beth Stadler, Murat Can Kalem, Joel Waldfogel

GUESTS: Pam Wheelock, vice president, University Services; Jane Pribyl, finance director, Controller's Office; Mike Volna, associate vice president, Controller's Office; Debra Dykhuis, executive director, Human Research Protection; Monique MacKenzie, Director of Planning & Architecture, Capital Planning & Project Management; Melissa Anderson, associate dean, Graduate School

Professor Gini welcomed the committee.

1. Internal Sales Reports (ISOs) summary and status of recommendations

Gini welcomed Jane Pribyl, finance director, Controller's Office and Mike Volna, associate vice president, Controller's Office, who together with Sue Paulson, assistant controller, Controller's Office discussed a report conducted by Huron Consulting. Huron Consulting was engaged to review internal sales organization oversight and the compliance program that is in place. Volna said the Internal Service Organization (ISO) area was rather loosely defined in federal regulations, particularly what could be charged to sponsored projects. In conducting its evaluation, Huron used two scope questions:

1. In terms of compliance, has the University become too risk-averse in developing policies, procedures, and oversight mechanisms that relate ISOs?
2. In terms of processes and what we work with departments on, are there opportunities to be looking at doing things differently that will provide better service to them?

Volna said they wanted to focus on all ISOs when they first decided to conduct the report. However, Brian Herman, vice president, Research, wanted to focus on service centers and those ISOs that deliver a lot of research-related activities. Thirty ISOs that focused on research activities were chosen out of 150, and Volna said this helped prioritize what they would look at.

Volna directed committee members' attention to a presentation, which included the following:

Current environment:

- Approximately 150 units providing services for a fee to other university departments
- Financial oversight of ISOs is largely provided by local budget/finance offices (RRCs)
- Robust policy and procedure framework in place at University of Minnesota
- Internal/External Sales Office (I/ES), within the Controller's Office provides policy and compliance oversight

Suzanne Paulson then discussed Huron's observations, and also directed committee members' attention to the presentation. Huron's conclusions included:

Compliance: *"The U of M's approach to compliance is in line with federal regulatory requirements; indeed, UMN's oversight is more extensive than many other research institutions."*

Process Enhancement: *"Opportunities do exist, but I/ES (Internal & External Sales) has incorporated and facilitated significant improvements in the last several years."*

Huron's recommendations:

Compliance: Formalize and implement the proposed policy and procedure changes that are currently in draft format.

Process Enhancement:

- Enhance collaboration between the ISOs, especially among the smaller units, to share best practices and consider common systems and processes
- Explore the concept of a "shared service center" which would provide rate calculations, billing and reconciliation for multiple ISOs potentially freeing up resources to focus on ISO service within the ISO
- Continue to enhance customer service to ISOs

Other: Consider formalizing a competitive process for OVPR to provide financial support to research ISOs.

Paulson discussed Huron's suggestions to consider, including

- Reduce frequency of rate reviews
- Reduce detailed reviews for ISOs' having no past compliance issues
- Stretch the period for recovering initial costs, surpluses, deficits over multiple years (vs. one year)

- Possibility of building future capital investments into ISO rates (for non-federal & external customers)

Additional service enhancements:

- Improve equipment processes – timeliness of tagging
- Further refine policies related to asset trade-ins
- Adopt “differential depreciation schedules” for highly-specialized research equipment
- Expediting review and negotiation of contracts
- Training & education related to financial reporting for ISOs (e.g., budget to actual)

Jane Pribyl then discussed the implementation plan, which included classifying and prioritizing six primary Huron recommendations. Internal sales policy pending changes include:

- Lengthen frequency of reviewing and updating rates
- Remove requirements for annual review by the deans
- Established risk-based approach
- Relaxed business plan requirements
- Relaxed training requirements
- Clarification provided in areas that had frequent questions

Gini thanked Volna, Paulson and Pribyl for the information.

2. Psychiatry clinical trials case and University reforms

Brian Herman, vice president, Research, and Debra Dykhuis, executive director, Human Research Protection Program, discussed the psychiatry clinical trials case, and directed committee members’ attention to a slide presentation.

Background:

- Dan Markingson committed suicide in 2004 while enrolled in a clinical trial at the University
- Markingson’s family, some faculty, and others in the broader community raised concerns centered on:
 - Whether consent was appropriate and ethical
 - Conflict of interest with the principal investigator
 - The University’s response to his family
- Two external reviews launched

Herman went on to review the independent, external panel process:

- December 2013 Faculty Senate resolution
 - Focused on current practices and individuals with diminished decision-making capabilities
- University supported resolution and undertook review
 - Contracted with AAHRPP to manage
 - Six independent experts retained to conduct review

- Review completed February 2015 and presented to the Faculty Senate March 6, 2015

Herman said the external review panel recommendations and themes included the following:

- IRB membership and review process
- Education and training
- Scientific review
- Monitoring
- Engagement: research subjects and community
- Consent
- Culture and leadership

Herman gave an overview of the legislative auditor review:

- 2014 legislative request to the Auditor
- Launched June 2014
- Requested and received thousands of pages of documents, visited campus, interviewed individuals
- Focused on the circumstances surrounding Markingson's death in 2004

Office of the Legislative Auditor (OLA) Recommendations:

- Implement external review report recommendations
- Have the Office of the Ombudsman for Mental Health and Development Disabilities monitor patients in Department of Psychiatry drug studies
- Legislation to require and direct changes

Herman went on to discuss the current state of the case:

- Herman and Brooks Jackson, dean, Medical School and vice president, charged by President Kaler to implement recommendations
- Implementation Team appointed and active
 - Chaired by Mayo IRB
 - Cross-section of dedicated individuals, including external and internal stakeholders
- Significant negative press environment
- Resignation of Dr. Schultz as department chair
- Suspended enrollment of approximately 17 psychiatric drug interventional trials, which are being sent for review to an outside IRB
- Urgency to resume enrollment in suspended studies

Implementation work team:

- Work plan by May 15 with accountability metrics, with short and long term action items across the University
 - Likely this will be open for public comment for a period of time, so faculty and other interested parties can comment on the plan
- Analysis of the resources needed to implement the plan

- Review of best practices on managing conflicts of interest and organizational or structural changes that would improve processes
- Form a committee of external experts and community members to provide input into the University's Human Research Protection Program (HRPP)

Herman went on to review what was currently in progress:

- Structural and composition changes to the biomedical IRB
- Changes to IRB process and documentation
- Enhancements to post-approval review, education, and training staffing
- Policy changes related to subjects with diminished capacity to consent and Legally Authorized Representatives
- Independent IRB, Quorum, signed to review current suspended study environment

What the community can expect:

- Psychiatry suspended studies get reviewed
- A slow-down of negative press
- Continue to move forward aggressively and productively
- A period of growth and change
- Frequent, transparent communication
- Enhanced oversight

Herman directed people to <http://research.umn.edu/advancehsr/> as a comprehensive resource for the implementation team charge, chronology of events, and a library of all key events.

Professor Ly discussed possible conflict of interest issues, and said he was glad to know that the University was going to address all the issues in the planned forums. Herman said they had done a couple of things regarding conflict of interest: they had asked every member of the implementation team to list their industry engagements from the past five years and if they have taken any personal consulting money. They have also asked the Conflict of Interest Program to review the information to see it meets the University's definition of conflict of interest. Herman noted no one on the committee had a conflict of interest that prevented them from serving on the committee, and he emphasized it was important to carefully consider if something was really a conflict of interest versus a misunderstanding of the facts.

Daniel Habchi asked what criticism Herman felt was unwarranted or unduly extreme. Herman replied that the calls in the lay press for President Kaler's resignation had been inappropriate, and allegations about people on the implementation team were inaccurate. Gini noted there was so much in the press it was difficult to avoid reading about it. Herman emphasized there were a lot of good people doing a lot of good work and working very hard to ensure things were done as well as possible, and Herman added the external panel report said as much.

Professor Kyba asked for clarification about the delay, saying the initial event occurred in 2004 and the report was commissioned just two years ago. Herman said there had been a lot of activity around the issue over the past decade, and the main issues were around consent and coercion.

The issues were if Markingson was appropriately consented, as he was a person with a mental disorder, and whether there was coercion for him to remain in the study or if he was free to leave the study. Herman said the FDA conducted an audit and did not find any evidence that Markingson was inappropriately consented. The Hennepin County and Dakota County court systems also reviewed the situation and felt Markingson was competent and not under any duress in making his own decisions about being part of the trial. However, Herman said, his family, his mother in particular, was very concerned about his symptoms and attempted to talk to the investigative team. Many on Markingson's team, including his halfway house, his psychiatrist, social worker, and psychologist all felt he was getting better on his therapy. Herman went on to note that schizophrenia is a very difficult disease to treat successfully: approximately 40% try to commit suicide and approximately 15% succeed.

Kyba noted the press said the IRB did not have expertise to evaluate the study, and asked if that criticism was warranted. Herman said he did not know who was on the IRB at the point they reviewed the study. However, the IRB considered the allegation and decided there was no basis for it, but did not follow through with any inquiry or investigation. Professor Vaughan acknowledged the tragedy of the situation, and asked what kinds of trends, if any, the situation uncovered. Vaughan added in any kind of investigation, weak points would be found but he wondered if it was something wrong in the University's approach or something that would be classified as an anecdotal tragedy. Dykhuis said in looking at the IRB through the lens of the external advisory panel, and using the test of making the program beyond reproach, there are clearly things that the University could do better. However, she noted, there was no way to say if there might have been a different outcome if any of the improvements had been applied sooner. Vaughan then asked if there was a risk of overreacting to one event to the burden of the rest of the investigators at the University. Dykhuis acknowledged the possibility of such risk, and said they wanted to guard against superfluous bureaucratic mechanisms.

Herman pointed out there had been two deaths in all the psychiatric clinical research at the University since 2004: one was Markingson and the second was a person who died from cancer while in the trial. Herman said the auditor's report clearly stated Markingson's death could not be declared a sequela of participating in the trial. Herman agreed that as the University moved forward there was not unnecessary burden to individuals, and Herman emphasized that research was essential at the University and was strongly supported by the institution.

Gini said an article in the New York Times enumerated several damaging points, and she felt it all came down to "follow the money." Sometimes subjects enroll in a study because they get paid, and there are signs that point to conflict of interest, Gini said. Herman said this particular trial was a multi-institutional study run by a principal investigator at Columbia University. The University of Minnesota was one site out of 26, which meant 26 IRBs approved the same protocol that was in place at UMN. Herman said in the study to which the NY Times referred, that of Seroquel for borderline personality disorder (BPD), there was a fundamental question about whether anything pharmacological works for BPD. The maker of Seroquel is the same company with which Dr. Charles Schultz, head of the Department of Psychiatry at the time, had a public consulting arrangement. Technically, Herman said, Schultz did not get any money at the time. However, Herman said he felt it was appropriate to reimburse people for travel and costs associated with the study. Another issue that came up, Herman continued, was how the people in the halfway house where Markingson lived were classified, and if it met the definition of

“prisoner,” for whom there are different guidelines. The University legal team determined they did not qualify as prisoners, so they were not under the same kind of restrictions. Additionally, Herman said, the halfway house was an outpatient facility from which patients were free to come and go as they wished. Thus, Herman said, they had no control over them and what they did with their medications. There will always be conflict of interest issues, Herman noted, and they need to be managed as appropriately as possible. Herman also noted the NY Times did not fully publish all of the information.

Professor Orf asked if there would be communication as the University moved forward on all the guidelines. Herman said he was certain the University would try to announce the major changes and results of those changes, however, what the press did or did not do was difficult to predict. Herman noted there had been several documents released by the University thus far that had attempted to present the facts, and Herman reiterated the documents were on the website.

3. The University working with a 501c3 organization

Herman went on to discuss the University working with a 5013C Organization as part of efforts to enhance public/private partnerships. He noted they had been reaching out to industry colleagues, faculty, and students about how to provide more value to them and gain better partnerships with industry. Herman said that industry had expressed interest in providing data that University faculty would have access competitors would not. One of the best ways to do this, Herman said, was to establish a 501(3)C organization that sits legally outside of the university. This establishes some legal protections for data access requests.

Herman said the Battelle Corporation was a company that had formed a number of joint ventures with universities that allow for protecting the proprietary data. There are opportunities to combine the capabilities of the Battelle organization with the capabilities of the University faculty, Herman said. The goal was to work with Battelle to see if the University could create a 501(3)C as a jointly owned venture, which would:

- Allow the University to store proprietary commercial data
- Allow the faculty to access the data and do research on that data
- Provide it back to the companies without the potential for openness under the data practices act

Herman said they would model the partnership off the other universities with which Battelle has partnered. Herman added it would be an interesting way to enhance the faculty’s access to interesting data and information, and at the same time strengthen the public/private partnership. This in turn could lead to more revenues and more funding. Herman emphasized it was a win-win for faculty and for the University, and that was the philosophy and rationale for wanting to do something like this.

Gini asked who paid for what in the process. Herman said the University would pay for its portion of the faculty effort, and Battelle would pay for theirs. It would be no different than other kinds of partnerships they have around intellectual property, he said. To Lisa Johnston’s query, Herman said data could be de-identified in a way that was available for publication, and there were no publication restrictions on the academic faculty side in such a partnership. If Battelle

turned out to develop a propriety product on their own as part of the partnership, that would be something they would own.

Professor Zelazo asked to what extent the University needed this kind of company, saying it seemed that creating a 501C and a repository for data created through University could be done without such a company. Herman noted there were excellent models where it had worked already, so the company already knew how to do it and could get it done relatively quickly. Second, companies in particular are driving the effort because they do not believe that University has sole control over its data. Part of this, Herman said, was creating a comfort level with the companies to provide their data in a structure and an entity with which they are familiar. Herman said it would take years to figure out such legal aspects, and companies like Battelle have already figured it out.

Herman reiterated that the sole purpose of working with this structure was to provide a resource of a secure environment where proprietary data could be stored. Battelle has done this with other universities and it had not affected the ability of faculty to start companies. Hinh Ly asked if Battelle would fund faculty and Herman replied it was a possibility.

4. Capital planning and building expansion as it relates to research

Herman went on to discuss capital planning and building expansion as it concerned research. The University has approximately 29M square feet, a significant portion of which is research, and Herman expressed strong concern that much of that is quite old and non-functional for today's research. Herman said Pam Wheelock, vice president, University Services, and her team had been looking at the issues, considering processes for more engagement, and present recommendations on how the University should think about space planning and its effects on the research enterprise.

Wheelock presented background on the issues, and directed committee members' attention to a presentation. She said they struggled to maintain the physical structures the University already had and extend and preserve their useful life. However, there is limited capability to do that, as federal funds are for research and not for facility infrastructure. Wheelock said there were only two primary sources of funding for buildings: student tuition, and taxpayer support, i.e., state appropriations. There are, Wheelock added, occasional gifts from donors that might help.

Wheelock reviewed the space planning approach:

- Space is a critical tool for supporting academic programs
- Space plays a major role in the student experience
- Space can be a competitive advantage
 - Recruiting students, faculty, and staff
 - Obtaining grants and gifts
- Space is a major University expense
 - Construction and renovation
 - Operations and maintenance
 - Utilities, interest on debt, lease payments

Space Utilization Principles:

- **Aligned:** The University should provide the correct type, quality, and quantity of space required for people and programs to function effectively
- **Financially Sustainable:** The University should not have more space than it can afford to operate, maintain, and support
- **Managed:** The University should provide tools and incentives for maximizing the efficiency and effectiveness of its space resources

Wheelock compared the buildings across the campuses in terms of square footage, estimated replacement value, projected 10-year needs, and 10-year needs/replacement value (FCNI). She discussed how capital need exceeded available funding, and stated the renewal funding gap: the University would need to invest an additional \$4.50 per square foot every year to sustain current condition.

Monique MacKenzie, Director of Planning & Architecture, went on to review statistics on the University's current space, and compared system space by use 2002 versus 2012. She then discussed current strategies:

- Focus capital investment by emphasizing renewal, replacement, and space efficiency projects in capital planning and state capital requests.
- Develop new mission-aligned space management tools, including Enterprise Asset Management (EAM).
- Continue to decommission as appropriate and invest in buildings best suited to flexible and adaptable use over time, using Building by Building Strategy

MacKenzie discussed the investment in existing space versus new space, and reviewed a building-by-building investment model. She then enumerated the next steps:

- Data system management tools and reporting
- Six year plan - capital planning
- Building by building strategy EAM

Herman noted a fundamental problem: when those who own a particular space have budget shortfalls, the institution assists them. Thus, there is little incentive to effect efficient use of the space. Herman also said there was a lot of old space that was not useful in today's and tomorrow's education and the research service mission to the university. Nor, he added, do they do not have any concept of how well the utilization of space occurs.

Vaughan asked if the University had been compared to other similar institutions, and Wheelock said the University's issues were fairly comparable to peer institutions. She said some institutions were looking at changes around student housing and creating multi-use spaces. Wheelock said they were now conducting a building-by-building investment plan. They are working toward collecting all the data they have about a building, getting information from building staff about adaptability and flexibility of the space, and putting all the data in one place. This will create a more reliable picture of whether a building is on the path to replacement,

whether it will be eliminated, or whether the building is in it for the long haul and can be a functional space.

Herman went on to say that research space comprises 18% of campus, and 70% of that is over 50 years old. He reiterated that HEAPR (Higher Education Assets Preservation and Renovation) was about one-third of what was needed just to maintain the space the University currently had. It is a real challenge, Herman said, to manage space, and visionary strategic thinking was needed about how the institution used space.

5. Graduate school and preparation of postdoctoral students

Gini welcomed Melissa Anderson, associate dean, Graduate School, who gave background on postdoctoral students and postdoc issues. She said the Office of Postdoctoral Affairs was established in 2002, and since then they had been looking at several issues. Over the past two years, they had been focusing on two in particular:

- Benefits, especially health benefits
- Professional development opportunities

Anderson discussed health benefits, saying that several years ago the University had looked into providing health insurance through Garnett-Powers & Associates, a company that provides health insurance nationwide to postdocs. However, they chose not to go that route, Anderson said, noting that postdoc associates and postdoc fellows may not be covered in the same ways that made Garnett-Powers an attractive alternative.

Anderson said another issue was the changes in benefits when postdoc appointments change. Over a 5-year period, 7% of the people who started as a postdoc had to transition health plans due to a change in their appointment. Many of those transitions are rough, Anderson emphasized, because of a lack of coverage during the transition or in dealing with the system itself. To Professor Kyba's question, Anderson clarified that not every transition required a change in health plan. She went on to say they were working on making such transitions smoother. An additional complicating issue is research fellows and research associates, who, by custom have been considered postdocs but are not. Nicole Victoria offered her own experience, saying the transition was very slow and she was without insurance for six weeks despite multiple visits to the office and multiple phone calls. She had pressing medical needs and had appointments pending, for which she needed fast tracking. Victoria added it took significant time away from research work, and it could have had negative and expensive impact on her health.

Anderson went on to discuss professional development, saying the graduate schools had renewed interest in it and it had been ramped up considerably this year. Anderson said they offered:

- A job search series
- A survival skills series
- Career week
- Career networking
- And numerous additional workshops and events

Anderson said they were also developing an advisory group to bring faculty, administrators and postdocs together to advise on issues. A campus postdoc survey was recently completed from which they'd garnered excellent feedback, Anderson said. Three issues stood out from the survey: job prospects, pay, and benefits, including retirement. Anderson said that some postdoc respondents indicated that they feel a lack of respect from others. . Victoria added there needed to be a dedicated staff and/or office for postdoctoral affairs.

Gini thanked Anderson for the information

6. Resolution: Parental Leave Benefits

The committee voted unanimously to approve a resolution that charging parental leaves as a direct cost creates a financial burden and an unfunded mandate on individual units or research projects, and should be paid out of central budget. The resolution will be forward to the Faculty Consultative Committee (FCC).

Hearing no further business, Gini adjourned the meeting.

Mary Jo Pehl
University Senate