SENATE RESEARCH COMMITTEE (SRC)
Meeting Minutes
September 14, 2015

[These notes reflect discussion and debate at a retreat 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 notes: late proposals; individual Conflict of Interest policy; MnDrive initiative; implementation of IRB activities]

PRESENT: LaDora Thompson, chair; Jeannette Gundel, Philip Zelazo, Claire Stewart, Lisa Johnston, Michael Kyba, Bill Arnold, Joel Waldfogel, Tasoulla Hadjiyanni, Jayne Fulkerson, Nelson Rhodus, Daniel Habchi, Suzanne Paulson, Logan Spector, Terri Rose Hellicant, Carol Carrier (for Al Levine), Frances Lawrenz, Lynn Zentner, Hinh Ly

REGRETS: James Orf, Murat Kalem, Bob Lewis, Elizabeth Steiner

ABSENT: Brian Herman, Tucker LeBien, Bethanie Stadler, Helen Ofstad, Gregory Cuomo, Jeffry Simpson, Rachel Bergerson

GUESTS: Michelle LaRue, research, Office of the Vice President for Research; Pamela Webb, associate vice president, Research; Jon Guden, associate director, Conflict of Interest Program; Lisa Warren, assistant vice president, OVPR; Emily Lawrence, chief of staff, Medical School Dean's Office

Professor Thompson welcomed the committee, and committee members introduced themselves. Thompson said it would be an exciting and opportune year for the committee to make an impact on the issues coming forth. Thompson emphasized the importance of data for any decisions the committee made, and the importance of being well informed on the issues.

1. Late research proposals

Thompson welcomed Pamela Webb, associate vice president, Research, who discussed the issues around research proposals being submitted late to Sponsored Projects Administration (SPA). Webb directed committee members' attention to a presentation, which provided background on the issue, and said she sought feedback from the committee about the plan to deal with late proposals. Late proposals were those that arrived SPA later than the published internal deadline, and did not refer to a proposal that failed to meet a sponsor's deadline, Webb noted. This meant SPA could not turn the proposals around in time to adequately review them.

Webb described what SPA had been experiencing with late proposals:

- The overall volume of proposals had increased 6%
- There had been a significant growth in the percentage of late proposals:
    - 1127 in 2014, compared to 884 in 2012
    - This is a 30% increase in late proposals

Significant growth in the percentage of late proposals

- 16.76% in 2012
- 16.46% in 2013
- 20.19% in 2014

To the committee's question, Webb said she did not have data as to the success rate of on-time proposals versus late proposals. She went on to illustrate how the grants landscape had changed since 2006:

- The system at grants.gov was no longer novel
- SPA must use 75 different electronic agency proposal submission systems
    - 20 more than just two years ago
- Additional regulatory requirements (e.g., FCOI, sub awards, data management plans) have increased the number of items to review
- Federal regulations require institutional proposal review to "ensure adherence to all regulatory and agency requirements"
- The National Science Foundation (NSF) had added extensive electronic controls which prevent SPA from submitting and removing a five-day post-deadline SPA certification window

Webb demonstrated the www.grants.gov process and proposal deadlines at other institutions. To the committee's questions, Webb said that when SPA receives a late proposal they do their best to turn it around in time. However, with the new Uniform Guidance Policies, there were specific reviews that must take place to meet all the requirements. For example, NIH's specific language indicates SPA is responsible for verifying conformity with the most current guidelines for all administrative, fiscal, and scientific information in the application. Webb also cited the False Claims Act, which states legal action could be taken if information was purposefully falsified and if they were knowingly in violation of the act.

Webb then discussed the proposed changes:

1. Change SPA proposal deadline to three working days for ALL proposals (due at 9:00 am)
    a. Proposals that must be submitted by Friday at 5:00 pm would be due to SPA by Wednesday at 9:00 am

2. Broaden and improve the notification process:
    a. Eliminate the previous late proposal warnings
    b. Replace with notification emails sent monthly:
    c. 1st late proposal: Reminder to PI of SPA deadline
    d. 2nd late: Reminder to PI, copying dept. head/chair
    e. 3rd late: Request to dept. head/chair for help to address issue, copying PI and Research Associate Dean
    f. 4th late: Request for corrective action plan from the PI to the Research Associate Dean, dept. head/chair, AVP-RA

Committee members were not clear that there were actually problems and felt they would be self-correcting once a deadline is missed and consequences were experienced. Webb emphasized the issue that SPA was not able to conduct a review of late proposals required by granting agencies. In fact, Webb noted, the University of Minnesota was cited in a NSF audit for inadequate review. Webb said there were other attendant issues, such as staff turnover and low

pay for staff. She noted that in the employee engagement survey, staff cited inadequate time to properly conduct the reviews. Moreover, agencies were becoming more and more stringent and SPA needed enough time to complete their part of the process.

Webb then briefly described the anticipated implementation of the proposed changes:

- Obtain input and refine the plan as needed (September 2015)
- Communicate planned change (October 2015)
- Implement new deadline policy (January 2016)

Professor Kyba said he felt it would be more helpful for investigators to hear why it was a problem for SPA rather than receive what he considered pestering emails. He also felt it was a self-correcting problem: once a grant deadline was missed and a grant was not received, the researcher would not make the same mistake twice. Kyba then asked if there was a way to submit the majority of the application and have it processed for institutional compliance issues, and then submit the research plan later. Webb said that was what she wanted to do in the long term, and they were looking at electronic proposal and submission systems that would separate the science and administrative components. However, Webb noted, many of the error warnings they got were about the science piece. Committee members noted that proposal applications had become more complicated, which impacted the process. Webb acknowledged that both the science and administrative pieces had indeed become more complex.

Thompson asked the committee if there were any objections to the three-day rule proposed for proposal submission, and there were no objections from the committee.

Thompson thanked Webb for the information.

2. Individual Conflict of Interest Policy

Thompson welcomed Lynn Zentner, director, and Jon Guden, associate director, Office of Institutional Compliance, and conveyed a brief message from Professor Will Durfee, who was unable to attend the meeting, about the conflict of interest (COI) policy. Durfee conveyed to the committee that the new policy was a combination of two previous policies, and it made a number of policy fixes that had arisen over the years. It also made it more current and made changes for investigators who conducted human subject research.

Zentner provided background, and said in fall of 2010-2011, two COI policies were rolled out. The consensus since then had been that people preferred a single policy encompassing the different requirements. Zentner said they had made provisions and changes to clarify requirements; built in the PHS requirements that came into effect about three years ago; added some definitions; and loosened up in some areas. She said the way policies were changed and revised goes not only through review and input from the Senate Research Committee, but also the Senate Committee on Faculty Affairs (SCFA). Zentner noted this COI policy would ultimately go to the Faculty Senate for review later in the year, then back to the Senate for a vote in early 2016. The policy would also go before the President's policy committee.

Guden then reviewed the changes in the policy in detail, referring to a document sent to committee members.
(https://drive.google.com/open?id=0B5iPRGAHHPpwQzNWS1hMWmJZX1E)

Guden asked for the committee's feedback on the changes, and Zentner added that input was welcome at any time as it would be a long vetting process.

Webb expressed concern about the travel restrictions as she sits on boards, which are professional obligations, and they pay for her travel. She noted a fee or honorarium would need to be reported, but said she couldn't imagine anyone would be interested in travel to a professional obligation and spend its resources reviewing such items. Zentner said they would pass that along and such feedback was very useful. She noted that the definition of "business entity" tends to be broader than "for-profit" industry or company, and that they did not have that quite aligned with what might be the product of a professional association. Webb said that a lot of faculty had involvement in their professional associations, and Guden acknowledged this. The committee expressed concern about instances where a professional conference might be sponsored by a business entity, and wondered if it was a conflict of interest to present information at the conference. Zentner said her understanding was that while a person was on a study sponsored by an external entity, profit or non-profit, one could not accept the extra benefits. However, once a researcher had published on a study and there was no more opportunity to influence the outcome, there was not an issue. Thus, the clarification needed to be that sponsoring the research makes it a conflict of interest, and Zentner said there needed to be more dialogue around the issue for clarification. Guden returned to the definition of business entity, and said they were proposing to use the same definition that is in the Board of Regents policy. The committee discussed the description "presentation at events" and Zentner said there should be clarification around that as well.

Thompson encouraged committee members to continue to review the document and share it with colleagues, and communicate concerns to Guden and Zentner. Thompson thanked them for the information and discussion.

3. MnDrive initiative

Frances Lawrenz, associate vice president, Office of the Vice President for Research, presented background on the MnDrive Initiative. She referred the committee to the website, mndrive.umn.edu, said MnDrive was a partnership between the University of Minnesota and the state which aligns areas of the University's strengths with the state's key and emerging industries to produce breakthrough research around the state's and society's greatest challenges. In 2013, the Minnesota Legislature authorized a $35.7M biennial investment in four University research areas:

- Robotics, sensors and advanced manufacturing
- Global food ventures
- Advancing industry, conserving our environment
- Discoveries and treatments for brain conditions

Michelle LaRue, researcher, OVPR, continued with an overview of the program:

- MnDRIVE has funded more than 210 projects across the four research areas involving 629 researchers in 103 departments, 21 colleges and three campuses (Twin Cities, Duluth and Morris)
- Number of MnDRIVE Projects: 210
- Total People Hired: 321
    - Faculty: 28
- Graduate Students: 112
- Undergraduate Students: 63
- Post-docs & Clinical Fellows: 54
- Staff & Technicians: 64
- Publications: 638
- Number of Invention Disclosures: 41
- Successful External Proposals $57M
- Outreach, Meetings, Conferences: 500
- Number of People Reached: 30,000
- Students Graduated: 11

LaRue then enumerated highlights of the program:

- Three startup companies and nonprofits were created, including a medical device company and a startup that develops probiotics for use in turkey farming.
- Widespread international outreach, with internships in Germany and public seminars in Uganda.
- Engaged more than 144 external partners, including 3M, Boston Scientific, Syngenta, Tonka Waters, and Toro.
- External funding increased nearly seven fold during the second year of the initiative (from $7.3M in year one).
- More than 80 participants enrolled in neuromodulation clinical trials and more than 50 patients were treated with non-pharmaceutical therapies, and surgeries for brain conditions.
- A team of undergraduate students working on MnDRIVE projects won the national iGEM (International Genetically Engineered Machines) competition for a project that focused on bioremediation of mercury from contaminated water.
- Of the six students working on MnDRIVE projects who went into industry after graduation, 100 percent were employed by Minnesota industries.

The committee discussed the information, first asking about the published articles. Most journals were not available to the public without a subscription, and there should be a way to collect the articles and/or create a depository so they are available without charge. Lawrenz acknowledged there should be a way to do this, and said some of them were open access journals.

The committee asked how the money was divided among the areas. Lawrenz said the state gave two years' funding, then there was a call for proposals from the four areas, and an external strategic advisory board reviewed the proposals and made suggestions as to what should be funded. Kyba asked if the money was spent on recruiting faculty or existing faculty, and Lawrenz said it was a combination. It was up to each area as to what they wanted to do with the money. Kyba expressed concern that this was not the right way to set funding priorities, saying one had to constantly sell their ideas to legislators who had random and various ideas about what

was important. Lawrenz said the MnDrive Initiative was separate from the University's regular budget support, and it was a new idea to convince the state of the value and worth of the many endeavors of the University. The four areas were viewed by the state as beneficial. Kyba said his concern was that there were things that were easier to sell in terms of getting funded, while other equally important things were harder to sell. He said there could be negative effects, and he was interested in encouraging that discussion.

Professor Logan Spector asked if they were now locked into those four areas. Lawrenz said the University was not yet clear on how they might move forward but that there would be another request to the Legislature. Lawrenz acknowledged there had been legitimate questioning as to why those four areas had been selected. However, she noted, the initiative had been successful, the legislature was supportive, businesses were appreciative, and there might be opportunities to increase funding as they moved forward. Professor Nelson Rhodus wondered how the initiative intersected with the grand challenges, and noted that part of the goal might be that once these self-perpetuating programs get going, people driving the research could apply for independent grants. Thompson said she had a MnDrive hire, and she was under the impression that MnDrive money was really only for a four-year period, with 100% for the first year and decreasing in the following years. Lawrenz told Thompson she should talk to her college to clarify this. The committee asked if there was a strategy from keeping the money being taken out of the general appropriation. Lawrenz said it was a separate legislative action and not reported with the general University budget, but agreed it was important to monitor it. Lawrenz said to email her with any further questions and thanked the committee for the discussion. Thompson thanked Lawrenz for the discussion.

4. Implementation process of IRB activities

Thompson welcomed Lisa Warren, assistant vice president, OVPR, and Emily Lawrence, chief of staff, Medical School Dean's Office, to discuss the implementation process of Independent Review Board (IRB) activities. Thompson noted it was her understanding that many of the discussions and activities around the IRB situation had been funneled through FCC to this point. The SRC would now be the main point of entry with the issues and discussions, and Thompson reiterated the committee could be a significant voice in how the faculty was feeling, especially regarding the increased burden on researchers.

Warren said they had gone through many different types of conversations over the last year relating to the human subjects protection program, and she gave a brief overview emphasizing that the process had been faculty involved, advised, and led.

Warren gave some brief background and directed committee members to the legislative report online: http://advance-hsr-alerts.umn.edu/2015/09/legislative-update-september-2015.html.

Background:

- In Spring 2014, a University implementation team was convened to review recommendations from the external review panel
- Monthly reports to the legislature were now required
- External review panel delivered 63 recommendations based on a University Senate resolution which was passed in 2013

- Recommendations were delivered to the University Senate in March 2014

Warren went on to say that they had:

- Updated two IRB policies (501 – Vulnerable Populations and 506 – Adults Lacking the Capacity and/or Adults with Diminished Capacity to Consent)
- These policies and the IRB form Appendix were revised to prohibit recruitment of persons temporarily confined under an involuntary medical hold (72 hour emergency hold, 12 hour "intent to leave" period, or 72 hour "intent to leave" period for persons with chemical dependency) into a psychiatric drug, device, or biologic trial.
    - IRB Form Appendix 1 (Populations with Additional Considerations) has been amended to restrict any member of the study team from participating in a decision to rescind or discontinue a medical hold before its expiration for a research study.

Warren noted these changes addressed the external review recommendation to develop standards that protect against real or perceived coercion in psychiatric treatment settings in which individuals may fear involuntary court proceedings. While not specifically referenced in the implementation team report, it was brought to the attention of the team at the end of the process and has been the subject of significant discussion inside and outside the University.

Warren went on to say they had engaged an external clinical and translational research management and consulting firm (Compass Point Research) to conduct a review of 100 random protocols to further ensure they had addressed issues of human participant protection. These protocols will be reviewed for compliance with institutional requirements, governing regulations, and good clinical practice. This was not specifically referenced in the work plan but was requested by the President and Board of Regents.

Warren and Lawrence said the first meeting of the committee working to develop the Fairview University Research Oversight Committee had met. That committee had been charged and membership formed, and planning was underway for a first meeting this fall.

They had also updated the website to reflect language changes adopted in the implementation work plan and to provide contact information, opportunities to sign up for progress reporting, and updates on the implementation work. Warren and Lawrence again suggested committee members visit the website and to contact them with any questions. Thompson acknowledged they had not allowed enough time for the discussion, and asked Warren and Lawrence to return. It was suggested that they return to discuss the issues topic by topic and discuss in depth. Thompson said another concern was dissemination of information to the faculty, and said that committee could consider how to affect that.

Hearing no further business, Thompson adjourned the meeting.

Mary Jo Pehl
University Senate Office