Senate Research Committee (SRC)
April 9, 2018
Minutes of the Meeting

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

[**In these minutes:** Policy Review: radiation safety policy; Single-IRB issue for multi-site studies, non-faculty submitting to IRB; System-wide Strategic Planning in Research and Discovery]

PRESENT: Bill Arnold (chair), Jennifer Franko, Sumanth Gopinath, Vladas Griskevicius, Tasoulla Hadjiyanni, Diana Karwan, Leslie Kennedy, Michael Kyba, Al Levine, Katsumi Matsumoto, Claudia Neuhauser, Julie Olson, Nelson Rhodus, Susannah Smith, Jamie Van Etten, Philip Zelazo

REGRETS: Chris Gass, Nicole Pilman, Dave Roberts, Harrison West

ABSENT: Kristine Burrack, Carol Carrier, Gregory Cuomo, Jeanette Gundel, Sidharth Gs, Boyd Kumher, Tucker LeBien, Teresa Rose-Hellekant, Jeffry Simpson, Logan Spector, Amrit Vasdev

GUESTS: Brian Vetter, director, Department of Radiation Safety; Debbie Dykhuis, executive director, Institutional Review Board, Office of the Vice President for Research; Frances Lawrenz, associate vice president, Office of the Vice President for Research

OTHERS ATTENDING: Amber Bathke, Joseph Gaugler, Janice Jaguszewski, Paige Rohman, Pamela Webb

Chair Bill Arnold welcomed the committee and the members introduced themselves.

1. Policy Review: Radiation Safety Policy
Brian Vetter, director, Department of Radiation Safety, introduced the Radiation Safety policy and explained that the language is updated every few years. He pointed out the following changes:

- Location updates (from Boynton Health to Thompson Center for Environmental Management);
- Language referencing Radiation Safety as a department rather than a division;
- Web links and name change updates.

He told members that there are no substantive or programmatic changes.

Arnold asked if there have been any recent radiation incidents. Vetter explained that most of what the department is required to report on comes out of the medical center, and they are patient-related incidents. He said there has been one incident since the last policy update where

there was a loss of control of radioactive material. It was during a lab cleanout, he explained, and some equipment that was intended to be retained ended up in the heap of scrap that was recycled. Vetter said the source of the material was never found, but it was a very small amount and there was no harm to the public.

Diana Karwan asked if there is a way for someone to purchase a piece of radioactive material without having to report it to the Radiation Safety department. Vetter explained that some manufacturers are able to buy a general license to sell radioactive products, and as a seller they have regulatory responsibilities, but that oversight cannot be guaranteed and sometimes that is lost on the end user. Vetter said that they generally do hear of purchases in the research community, and they record them in their inventory. But any help that they can get from researchers to report when these purchases are made is helpful to the department, he said.

2. Single-IRB issue for multi-site studies, non-faculty submitting to IRB

Arnold introduced Debbie Dykhuis, executive director, Institutional Review Board, Office of the Vice President for Research (OVPR), and Frances Lawrenz, associate vice president, OVPR, and explained that two questions were brought to him regardings IRBs: 1) why non-faculty members are not allowed to submit IRBs, and 2) how multi-site IRBs are determined.

Lawrenz explained that the restricted access for non-faculty members is not a reflection of a researcher's ability, but there are some instances where the person submitting an IRB may not be entirely qualified to be a Principal Investigator (PI) on a particular project, and in addition to this, the check is to ensure that a faculty member is aware of the IRB submission. In order to submit an IRB protocol as a non-faculty member, the researcher is required to send an email to Lawrenz along with a CV and a protocol letter from the researcher's department chair or center director, so they can verify that the researcher is qualified to act as a PI on the project, she explained. She said the approval typically takes one day. Lawrenz acknowledged that it is an additional hurdle, but said she has never denied anyone. Ultimately, the checks are in place to stop someone who is unqualified or whose department chair did not know that the researcher was conducting the work, Lawrenz explained.

Susannah Smith suggested that some P&A research positions should be redefined to be considered an IRB-approved researcher since the job descriptions explicitly state that the role is responsible for human subject research. Lawrenz said perhaps as the Ethical Oversight Submission System (ETHOS) becomes a more established tool at the University, the OVPR can consider integrating PeopleSoft coding to identify some job classifications as PI-qualified.

Regarding the second issue, Lawrenz said that the National Institute of Health (NIH) wants researchers to have a single IRB protocol when conducting a research trial at multiple sites. She explained that the University, along with the implementation team, decided that it wouldn't make sense for the institution to take on the role of being a single IRB in response to the new requirement. Alternatively, OVPR acquired the services of an external IRB, Lawrenz explained, so that if researchers want to have a single IRB for a multi-site trial, they can use Chesapeake IRB.

Arnold asked who pays for Chesapeake services. Lawrence explained that when NIH made this rule, they assumed that the institution would pay. Pamela Webb clarified that the traditional IRB services will continue to be paid for in the same manner that they have been expensed historically, but now the secondary reviews that are required for the additional sites can be direct-charged to the grant.

Leslie Kennedy asked if the Department of Veterans Affairs or additional Fairview sites count as multiple sites. Pamela Webb said she'd check on it. Joseph Gaugler said that in his experience, partnering with external organizations may be deemed a multi-site study by NIH. He added that it sometimes creates a disincentive for the researcher because the University wants to do community-engaged work, but the single-IRB issue adds an administrative barrier that has a substantial cost to a researcher's grant funding.

Webb explained that feedback on this issue has been provided to NIH by both administrators and faculty. Committee members agreed that the concept is really good, but on a granular level the implementation creates some issues. Webb explained that NIH has assured OVPR that they will consider feedback on how the change impacts grant budgets and research.

3. System-wide Strategic Planning in Research and Discovery
Al Levine, vice president, OVPR, presented the committee with the Systemwide Strategic Plan. He told members that the plan will be presented to Board of Regents for approval in September 2018.

Arnold asked if the plan was designed as a tool to take to state legislators to ask for more funding. Levine explained that the plan is state focused because legislators wants to know what the institution is doing for the state as a whole.

Michael Kyba cautioned projecting the priorities internally because they can appear limiting; however he agreed that it makes sense to provide priorities when requesting funds externally. Levine explained that there is creative-driven research and solution-driven research, both of which are important. He said in a University of our size, we need to have both.

Vladas Griskevicius asked why the strategic plan approach is different in higher education institutions rather than in the business world. Levine suggested that one reason is because the academic world encompasses a lot of goals. He added that the University does not dictate faculty research; some researchers chase dollars, and some researchers work on the same thing their entire careers, he said.

Zelazo asked Levine if he could anticipate what the final list of priorities would look like. Levine explained that President Kaler asked to see a list of eight to ten priorities, system-wide.

With no further business, Arnold adjourned the meeting.

Bobbie Erichsen
University Senate Office