Senate Research Committee (SRC)
April 15, 2019
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 views of, nor are they binding on the senate, the administration, or the Board of Regents.

[**In these minutes:** NIH Regarding Foreign Influence; IRB Process Update; Faculty Concerns with the Overall Clinical Trials Process; SRC Letter to President Kaler and President-Designate Gabel]

PRESENT: Philip Zelazo (chair), Bill Arnold, Linh Chau, Crystal Dyer, Jennifer Franko, Sumanth Gopinath, Diana Karwan, Leslie Kennedy, Michael Kyba, Tucker LeBien, Julie Olson, Nicole Pilman, Nelson Rhodus, Susannah Smith, Claire Stewart, Christian Teyssier, Kathleen Vohs, Pamela Webb, Carston Wagner

REGRETS: Tasoulla Hadjiyanni

ABSENT: Alex Ardagh, Carol Carrier, Greg Cuomo, Jeanette Gundel, Boyd Kumher, David Roberts, Teresa Rose-Hellekant, Vaybhav Shaw, Logan Spector, Harrison West

GUESTS: Michael Oakes, Associate Vice President for Research; Professor Margaret MacMillan, MD, Department of Pediatrics

OTHERS ATTENDING: Bri Kennedy

Chair Philip Zelazo welcomed the committee and the members introduced themselves.

1. National Institutes of Health (NIH) regarding foreign influence
Pamela Webb, associate vice president, SPA Management, told members that the long-awaited guide notice from NIH regarding definition changes has not been released yet, and is now expected sometime in the next three weeks. Webb provided a few changes that the institution is expecting to see.

- The definition of foregin component will likely not change. Webb explained that the definition states that in order to be considered a foreign component, a researcher must be conducting research outside of the United States. She noted that this is a positive outcome for the University.
- NIH will likely expand the requirement for support to more people on the award; Webb explained that support is currently only required for the Principal Investigator and key personnel. She said that the institution is hoping the requirement will include technicians and research scientists and exclude students.
- With the new changes, the institution will likely have to start reporting gifts and prizes.

Committee members discussed how frequently gifts are directed to the researcher versus the department. Webb told members that if NIH meets their time table, then the guidance should be out by May 3, 2019.

Webb also told members that the Department of Defense (DoD) will be releasing funding opportunity announcements, and there will be an obligation to do current and pending support on all of those. She cautioned that all funding opportunities will require this, moving forward; the DoD has indicated that this change will help manage foreign influence. She said the University is still working with the DoD to get a better sense of what that means.

2. Institutional Review Board (IRB) Process Update

Michael Oakes, Associate Vice President for Research, then joined the committee to share some of the things he has been focusing on to improve the IRB process. Oakes explained that since installing the Ethical Oversight Submission System (Ethos) four years ago, Debbie Dykuis, executive Director, IRB, has focused on managing research compliance and balancing the research risks while seeking a fast, more nimble, more customer service oriented IRB. One main focus for improvement has been to work on reducing the turnaround time for submission responses, he said. To start, the IRB has pulled a large data set to analyze where the delays are, and why they are happening; Oakes explained that the delays are highly variable. For instance, he said, the biomedical science submissions take significantly longer to process than other submissions. He then walked members through the different ways that the IRB measures delays, pointing out specifically where the delays are too long in the process, and stressed that he is working to resolve those issues.

Zelazo asked if there is a target turnaround time that the IRB is shooting for. Oakes explained that the average delay time is currently 74 days, and the immediate goal is to reduce that to 50 days. Long term, Oakes said, the goal will be to cut the delay time in half, to 35 days. To accomplish this, Oakes explained that more education and support for the application process is needed to ensure that the submissions are adequate for the review process. Oakes stressed that this will require a culture shift; sometimes applications are very messy, he cautioned, and that delays the process.

Oakes told members that there are a few other things that he is working on to help shorten the delay time as much as possible. Previously, he explained, when an application came into the IRB, there was a triage process in place wherein a senior board member would review the application and decide which member should work on the submission; that approach has recently changed. Now, the whole team is responsible for every application, he said, and the board members are incentivized to work as a team.

Michael Kyba commented that he is mostly hearing about IRB issues from colleagues that do clinical trials, and wondered how many in the biomedical submissions are for clinical trials protocols. Oakes guessed that in biomedical submissions, roughly 25% are for clinical trials. He acknowledged that the delay time can be longer for those submissions, and noted that the education and support initiatives will help ensure that the submissions are complete and accurate to avoid further delays in the review process.

3. Faculty concerns with the overall clinical trials process
Following Oakes' presentation, Professor Margaret MacMillan, MD, Department of Pediatrics introduced herself and presented members with Challenges of Clinical Research. She described for the committee what the regulatory, financial, expertise, and recruitment roadblocks are for clinical research.

MacMillian walked members through a timeline showing a research project she worked on for the Blood and Marrow Transplant Program, and expressed concern that the institution has added so many roadblocks to avoid risk that potential research partners from outside of the institution are discouraged from working within the timeline constraints that the University has set in place.

Kyba asked if there are specific things the institution is doing that are counterproductive. MacMilliam told the committee that there is a sense that the clinical research philosophy has changed. She acknowledged that there have been some bad players at the institution in the past, and as a result, the institution's scientific community has suffered for it because roadblocks have been put in place to avoid any risk to the University. She also stressed that there are too many layers of approval to go through before research can be fully conducted, which can be repetitive and lead to delays. The culture at the University is to be safe and say no to risks, and she opined that the University suffers for it. She added that the institution is doing no favors to the patients by saying no to novel research.

MacMillian also told members that it is difficult for people that are not involved in the research to understand the roadblocks. She added that a common rule about how many steps there should be to get research done will be helpful; the government now understands that there are too many steps, she said, and they are starting to look at multiple IRB solutions, which addresses these issues.

4. SRC Letter to President Kaler and President-Designate Gabel
Zelazo told committee members that he'd like to gather feedback for a letter to President Kaler and President-Designate Gabel reflecting on the institution's research accomplishments during the Kaler administration, and the research priorities for the future.

Webb handed out a collection of statistics detailing what research at the University looked like at the beginning of the Kaler administration versus what it looks like now. Committee members also discussed the following topics:

- Members agreed that the technology commercialization, MN drive and state funding statistics were notable.
- Members discussed the importance of recruiting top faculty talent by offering the University as a place for researchers to come to do novel research.
- Members discussed that the University is both an R1 institution, and a land grant University, which is unique and should be supported.
- Some members discussed that a new administration should prioritize a culture of discovery and serving patients over avoiding bad press and compliance issues.

- Members discussed the importance of online learning, and agreed that leadership should recognize the benefits of supporting alternative educational formats.
- Members also discussed the Grand Challenges, and how that initiative fits into the future at the University.

Zelazo told members that he will work on an initial draft of this letter and then distribute it for review and comments by the committee.

Zelazo thanked members for their service, and announced that Julie Olson will be chairing the Senate Research Committee in the 2019-20 academic year.

With no further business, Zelazo adjourned the meeting.

Bobbie Erichsen
University Senate Office