

SENATE RESEARCH COMMITTEE (SRC)
February 15, 2016
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 represents the views of, nor are they binding on, the Senate, the Administration, or the Board of Regents.

[**In these minutes:** Implementation Team Update; Copyright Ownership Policy; Department of Psychiatry Update; Fetal Tissue Statement; Research Openness Subcommittee Recommendation; New Business]

PRESENT: LaDora Thompson (chair), Lisa Johnston, Bob Lewis, Helen Ofstad, Brian Herman, Frances Lawrenz, Tucker LeBien, Claire Stewart, Lynn Zenter, Bill Arnold, Tasoulla Hadjiyanni, James Orf, Teresa Rose-Hellekant, Jeffry Simpson, Logan Spector, Bethanie Stadler, Joel Waldfoegel, Rachel Bergerson, Carol Carrier

REGRETS: Gregory Cuomo, Suzanne Paulson, Jeanette Gundel, Jayne Fulkerson, Michael Kyba, Hinh Le, Nelson Rhodus, Philip Zelazo, Daniel Habchi

ABSENT: Allen Levine, Murat Can Kalem, Elizabeth Steinert

GUESTS: Lynn Zentner, director, Office of Institutional Compliance; Ann Aronson, deputy chief of staff, Communications; Susan Wolf, chair, Consortium on Law and Values in Health, Environment & the Life Sciences; Wendy Lougee, University librarian; Nancy Sims, Copyright Program librarian; Marlo Welshons, assistant to Provost Hanson; Roberta Humphreys, Research Openness Subcommittee Chair

Chair Thompson welcomed the committee and members introduced themselves.

1. Cultivating a Culture of Ethics: Susan Wolf, chair, Consortium on Law and Values in Health, Environment & the Life Sciences, introduced Lynn Zentner, director, Office of Institutional Compliance, and Ann Aronson, deputy chief of staff, Communications, as co-leads on the Cultivating a Culture of Ethics work team. Wolf said the implementation Work Plan of June 11, 2015 calls for “cultivating a culture of ethics.” The Work Plan says, “The team recognizes the responsibility of the U of M and each individual research investigator to keep the rights and welfare of research participants at the center of all research activities. The U of M must maintain the highest ethical standards for the conduct of research with research participants. That culture will come from fostering University-wide conversations, better educating research investigators, and setting standards that commit the U of M to an ethical culture of accountability....”

Wolf shared a table indicating the scope of the work team’s efforts. She then focused her remarks on the December 2015 conference, a draft statement of “core commitments,” and the team’s recommendation that the University consider administering a survey on research climate. On the conference, Wolf said Brian Herman, vice president, Research (OVPR), asked the Consortium (as part of the effort of the work team on Cultivating a Culture of Ethics) to take the

lead in creating a national conference regarding ethical research with human participants. The Consortium convened a faculty planning committee. The goal of the conference was to bring top national experts to the University to discuss the state of the national conversation on research ethics – areas of agreement, areas of continuing debate, and best practices. The conference occurred in December; approximately 300 attended in person with 1,300 participating via webcast. The faculty planning committee has recommended that this conference become an annual half-day conference in the morning, encouraging individual units to initiate related afternoon activity on research ethics.

Wolf provided a draft statement developed by the work team entitled, “Promoting a Culture of Ethics in Research: Statement of Core Commitments.” She said the goal is to use this as a catalyst to initiate conversations and as a document that can be modified for use in strategic plans, on websites, and in other communications. She explained that the draft was adapted from the Work Plan of June 11, 2015. Wolf said that the work team would appreciate if the committee members could provide feedback on the handout in the next couple of weeks. The work team would like the document to reflect broad input. It was agreed that committee members would provide feedback directly to Wolf.

Wolf added that part of the work team’s effort is to identify metrics that would allow the University to benchmark itself. The work team has identified a validated instrument to assist in this effort, the Survey of Organizational Research Climate (SOuRCe). The work team has recommended use of this instrument to establish a baseline by which to assess the impact of interventions, to allow for unit comparison, and to allow for comparison to other universities.

Zentner added that since August 2015, the University has been reviewing the effectiveness of the Compliance Office in all respects. She said that, in comparison to other large universities, they are finding that the University is an outlier because its Compliance Program lacks an ethics component. She indicated that there is a push to create a committee to address ethics-related issues. Zentner invited committee members to work with her on compliance issues involving ethics. She and Wolf clarified that this review of the scope of the Compliance Office is not part of the effort of the work team on cultivating a culture of ethics.

2. Copyright Ownership Policy update: Wendy Lougee, University librarian; Nancy Sims, Copyright Program librarian; and, Marlo Welshons, assistant to Provost Hanson, joined the committee to discuss proposed policy changes to the Copyright Ownership Administrative Policy. The policy is due for review this year and a change is recommended.

Lougee explained that the University’s Intellectual Property Policy was revised in 2007, creating two separate policies: Copyright and Commercialization. The Copyright Policy gives faculty and faculty-like employees ownership of their academic works. The Commercialization Policy states that the University has ownership of technology, including software, but excluding works covered by the Copyright policy. Lougee explained that a committee was appointed to evaluate whether software can be considered an academic work and what ownership rights obtain. The committee concluded that in some disciplines software may be considered an academic work. Further, under federal law software, once written, is copyrighted and in more limited circumstances may be patented. The committee recommended that the Copyright Administrative

Policy be amended to clarify that faculty/faculty-like appointments hold the copyright in software that is an academic work. The University would own rights associated with patents/commercialization. Consequently, the software would be co-owned: copyright in the academic work owned by the faculty member, the University owning the patent rights. In practice, a faculty member wishing to commercialize software would turn over the copyright to the University.

Bethanie Stadler asked how the proposed policy affects students and their academic works. Lougee replied that the University Commercialization Policy changed in 2015 to reflect that, in general, students own the rights to the technology they create as part of a course requirement. Thompson asked about timing regarding the next steps for the policy change. Welshons said that if the policy moves through the process as planned, it would take effect after the thirty-day public review period, which would begin after the President's Policy Committee approves it on June 3rd.

3. Department of Psychiatry: Thompson explained that this agenda item was added because of recent activity and news reports surrounding the Department of Psychiatry. Herman said that an external review was performed on the Human Research Protection Program (HRPP) and the review resulted in President Kaler appointing an implementation team co-chaired by Brooks Jackson, dean, Medical School, and himself to implement the recommendations made by the external review panel. One of the recommendations was for the Clinical Transitional Science Institute (CTSI) to temporarily manage the clinical research studies in the Department of Psychiatry while it restructured. In order for CTSI to determine what steps were necessary to move the management and oversight of Department of Psychiatry trials to CTSI, they obtained an independent consultant. The consultant was charged with creating a management plan for the movement of the oversight responsibilities. The report of the consultant was delivered to the University around Christmas 2015, he said. Herman discussed the contents of the report and said no concerns regarding patient safety were found. He went on to discuss some of the difficulties in addressing some allegations in the consultant's report: namely, that specific instances of poor practice were not identified, so that the implementation team could not respond to them. Other concerns listed in the consultant's report were already in the process of being addressed. Warren reminded the committee that they had received the report the previous week and once the information enclosed in that report hit the news, Research worked hard to quickly provide information to stakeholders.

Thompson asked if they planned to bring a consultant in to evaluate the implementation plan. Herman responded that David Strauss is the consultant evaluating that progress. He is the vice chair for psychiatric research at Columbia University. Compass Research is also looking at 100 random clinical trials and then analyzing them to ensure they are performing as they should be. Warren said the legislative auditor is observing the University in this matter and there are hearings scheduled in both the Minnesota House and the Minnesota Senate to evaluate the topic.

4. Fetal Tissue Statement: Tucker LeBien, associate vice president of research, Academic Health Center, reviewed from the last meeting his detailed presentation regarding human fetal tissue research and the University position on its use in research. After the meeting, the committee finalized a resolution stating support of legal human fetal tissue research performed at

the University and passed it on to the FCC. LeBien said the FCC never sent a formal document to University administration. He said he is seeking clarification regarding where the resolution is. Thompson said she would follow up with FCC senate staff.

LeBien reported there is a formal process in place regarding how the University handles human fetal tissue and cells. The Anatomy Bequest Program will receive the tissue and properly and respectfully cremate and bury the remains in an unmarked grave. The Anatomy Bequest Program will track all cells throughout their entire use within the University.

LeBien added that the Board of Regents (BOR) received a letter from the United States House of Representatives Committee on Energy and Commerce regarding House Resolution (HR) 461, which created the Select Panel on Infant Lives and empowered the panel to investigate issues related to human fetal tissue research being conducted across the country. The letter requested a tremendous amount of information regarding human fetal tissue research performed at the University. He said a BOR hearing and potential vote on the use of human fetal tissue in research was not held as planned due to the letter and the subsequent request for information. Instead, the BOR released a statement that said investigators at the University have the right to perform research in any way that is legal and ethical. Professor Tasoulla Hadjiyanni expressed her opinion that the Board of Regents' and University representatives' language must reflect the opportunities such research provides for medical discoveries, rather than the University's 'right' to conduct such research. Herman said there are seven to eight bills being developed in the state legislature around this topic and he has meetings set up with Republican legislators who oppose the use of human fetal tissue for anything, including research.

5. Research Openness Subcommittee recommendation: Thompson reviewed the makeup and duties of the Research Openness Subcommittee. She explained that the subcommittee reviews applications for research exemption requests and brings its recommendations to the SRC. The SRC reviews the recommendation and then sends it to the Office of the Vice President of Research with its position on the subcommittee recommendation. Thompson thanked Research Openness Subcommittee Chair Roberta Humphreys for her work and asked her for the subcommittee's recommendation on an exemption proposal from Professor Graham Chandler. Humphreys said there were seven members in support of approval and two members who did not respond to the request to vote. The SRC voted all in favor to support the subcommittee decision to grant the exemption.

6. New Business: Thompson explained an investigator would be joining the committee in March to discuss the types of challenges small grant proposals pose within the University.

Thompson also said there is interest among members to discuss how the unionization of faculty might impact research at the University. Members expressed interest in having representatives from both the union and administration join the next meeting to present both sides of the argument for and against unionization.

Logan Spector provided an update regarding the Driven to Discover (D2D) building on the State Fair Grounds. He said the Council of Research Associate Deans (CRAD) sent a letter to Herman asking for funds to support D2D. OVPR is providing \$175,000 in funds and \$25,000 is being

requested from each college that utilizes the building. Dr. Frances Lawrenz explained that there is a problem with the contractual relationship with the State Fair. The problem is not obtaining funding; it is that the fair is seeking to restrict usage of the building. Discussions with the fair to come to a resolution are ongoing.

Hearing no further business, the meeting was adjourned.

Patricia Straub
University Senate Office