

Minutes*

**Senate Research Committee
Monday, January 23, 2012
2:15 - 4:00
238A Morrill Hall**

Present: Melissa Anderson (chair pro tem), Alvaro Alonso, Arlene Carney, Margaret Catambay, Paul Cleary, Jerry Cohen, Marc Dunham, Demoz Gebre, Maria Gini, Greg Haugstad, Seung-Ho Joo, Frances Lawrenz, Tucker LeBien, Jennifer Linde, Timothy Mulcahy, Federico Ponce de Leon, LaDora Thompson, Alexander Thorkelson, Thomas Vaughan, Kyla Wahlstrom, Karen Williams

Absent: Linda Bearinger, Anna Clark, Robin Dittman, Christopher Nappa, Kola Okuyemi, Lynn Zentner

Guests: Professors Susan Berry, Michael Oakes; Associate Vice President Pamela Webb

Other: none

[In these minutes: (1) Federal Demonstration Partnership Faculty Burden Survey; (2) IRB review of proposals not funded externally; (3) update on STAR METRICS]

1. Federal Demonstration Partnership (FDP) Faculty Burden Survey

Professor Anderson convened the meeting at 2:15, explained that Professor Bearinger was out of town, and welcomed Associate Vice President Webb to discuss the 2012 faculty burden survey from the Federal Demonstration Partnership (FDP).

Ms. Webb began by noting that Professor Cohen is the University's faculty representative to the FDP, a group of 119 research universities and 10 federal agencies dedicated to trying to streamline burdens on research while maintaining good stewardship of funds and the research. She and Professor Cohen, and others from the University, attend meetings about three times per year and participate in pilot projects sponsored by FDP.

The 2012 survey is a repeat of a survey administered in 2005 to 6,000 selected faculty members. This version is being sent to all PIs with federal research funds during 2010-11 at all 119 FDP member institutions. About 1300 people at the University of Minnesota will receive the survey this year; they will be informed about the survey by email from her and Professor Cohen and will be sent reminders if they do not respond. The survey will take place about March 1; Ms. Webb said she felt strongly about Minnesota faculty members responding because this is such a comprehensive institution—there are faculty members in areas of research that other institutions do not have, so faculty response from Minnesota can add depth to the survey results. It will take about 30 minutes to complete.

* 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.

Ms. Webb distributed a handout outlining the topics on the 2012 survey as well as information about how it will be conducted. She noted that the 2005 survey indicated that PIs spend 42% of their time on administrative tasks; that result had a huge impact and was used to talk about change. While no one says the administrative burden should be 0% of a PI's time, because there are functions that one must perform, there is the question about whether certain requirements are necessary and add value to the process. Professor Cohen reported that the faculty participants in FDP strongly endorse the survey. Ms. Webb also noted that the 2005 survey went primarily to senior white males; this one will go to everyone and there is a sense that women faculty and junior faculty had more administrative burdens than did senior faculty members.

Professor Vaughan inquired if there have been changes as a result of the 2005 survey findings. The federal government has added more regulations, Vice President Mulcahy commented. Ms. Webb said that if she were asked what rules and regulations have gone away in the last six years, she would have to be silent in response to the question.

Vice President Mulcahy said that the University is trying to streamline its own processes, because institutions can mitigate or worsen the impact of federal regulations. He agreed with Ms. Webb that the 42% figure did not have a big impact on federal decision-makers. The National Academies have suggested that public universities, under such financial stress, would be helped if the federal government were to fund all indirect costs appropriately; that will not happen but it appears that federal agencies have accepted the argument that they should reduce the regulatory burden. He encouraged faculty members to fill out the 2012 survey because the federal government listens when faculty responds.

Professor Anderson thanked Ms. Webb for her report and expressed hope that all faculty members would respond to the survey. Ms. Webb said she would bring a report back to the Committee when the results of the survey were known.

2. IRB Review of Proposals Not Funded Externally

Professor Anderson welcomed Professor Susan Berry (later joined by Professor Michael Oakes) to discuss IRB review of proposals not externally funded.

Professor Berry began by saying that this is an important issue for the protection of human subjects. Members of the Institutional Review Board (IRB) are charged with protecting human subjects; this is an institutional responsibility that they feel strongly about, and good science protects human subjects. If human subjects are asked to participate in a study where the science is inadequate or inappropriate, the subjects may be at risk and they cannot evaluate if the risk is acceptable. They need to know that the science underlying the research is of sufficient quality that there will be a benefit, if not to them personally, to the advancement of knowledge and/or treatment or prevention of disease. The IRB would prefer to not judge the science of applications; instead, it would prefer to focus attention on the protection of research subjects.

Many studies submitted to the IRB for ethical review have already undergone scientific review at the NIH or NSF or a philanthropic organization. The IRB accepts the results of any robust peer-review system.

But for a subset of studies submitted to the IRB, there is no prior scientific review and no robust means to judge the science. The biggest institutional risk occurs when an individual PI wants to try something out, do a pilot. The higher medical risks come with drug trials, which are usually done thoughtfully and are well-vetted—but often those doing the vetting have an interest in the outcome of the research, so independent review is needed. So while the IRB must vet the science in some cases; they want that done before a project comes to the IRB, although the IRB reserves the right to look at and be sure it is done.

The question is how to get robust scientific review completed before a medical study is submitted to the IRB. The IRB has asked departments to set up review processes for research that does not have external peer review; the results vary. Some are rigorous and regular, some are ad hoc but conscientious, and some have little or no scientific evaluation. Things need to change, but how?

One proposal is to work with the Clinical and Translational Science Institute (CTSI) as a potential site for scientific evaluation of research proposals submitted to the IRB but not otherwise reviewed. The CTSI reviews its own funded research, and the CTSI people have been asked if they could perform such evaluations more broadly. For the CTSI to review research such work would have to be research related to CTSI, Dr. Berry said; she did not believe it would evaluate all research and there may be research activities at the University such that CTSI would not be the appropriate venue for review. Dr. Berry said she and Professor Oakes are asking for a reasonable proposal to look at research projects and determine if they are worth doing; they need a more secure, robust assurance process to be certain that human subjects will be protected.

What about social-science research, Professor Alonso asked? CTSI would not review such research, Professor Berry said. Any proposal would require full committee review, but it is uncommon for social or behavioral research to carry such high impact. Professor Oakes said that the challenge on the social/behavioral side is that the research is so diverse; it comes from anthropology, economics, epidemiology, and so on; CTSI is not in a position to review it. There is currently no requirement for scientific review for such projects unless they have external reviews, so the IRB is trying to figure out if a review is necessary and, if so, how it might be done for research that incorporates human subjects beyond minimal risk. This is not about library research or survey research, and there is not a huge stream of risky social/behavioral research, but it does exist. The IRB is unsure how to solve the problem of scientific pre-review of more-than-minimal-risk social/behavioral research.

Most of the medically-related, more-than-minimal-risk research is now being addressed by improving departmental reviews, and—it is to be hoped—in the near future by the CTSI, Dr. Berry added; such reviews would cover the high-risk research.

Professor Vaughan noted that most of the discussion has been about risk; do they consider the benefits as well? That is always part of the review, Professor Berry said. They only insist that human subjects be informed about risk and also about the balance between risks and benefits. Professor Oakes said that the IRB looks at the risk versus the benefit, but without prior scientific review it can be difficult to assess the benefits; it is especially difficult to balance things in most social-behavioral research since benefits rarely accrue to subjects themselves. Again, Professor Oakes reiterated, the IRB would rather not assess the science and prefers to rely on expert assessment of benefits.

Some people have a vested interest in a project going forward, Professor Cohen said, and part of the problem is perception. Such conflicts of interest abound and trying to eliminate the problem is not easy because those with expertise are often closely associated with carrying out the research. He asked if they had given thought to how to eliminate the perception of bias when they receive proposals from departments with problems. CTSI would considerably reduce the potential for risk, Professor Berry said. Professor Oakes said that Professor Cohen is correct: Conflicts are everywhere but the members of the IRB, among others, believe that the institutional reputation is more important than an individual's potential gain or scientific reputation. Further, the potential for conflict of interest is part of the IRB review, Professor Berry said.

Professor Alonso said that if some departments review proposals well and others do not, it would be better to have a central office do them all well. That is what they hope to accomplish, Professor Berry said. It was not possible before the CTSA grant, which provided substantial infrastructure to the CTSI.

Professor Berry said she wanted the Committee to be aware of their concern and how they hope to address it—and why it could be a problem for the University if it is not addressed.

Professor Oakes commented that when it comes to scientific review there is an obvious point of tension with academic freedom. Someone wants to do a study and asks about the layers of bureaucracy that stand in the way. But instead of bureaucracy, Professor Oakes said, the IRB wants a system closer to peer review that deals with risk and conflicts of interest. When it comes to peer review of science, it helps to have another layer of review in addition to the IRB; it is interest of everyone to promote good science and the protection of human subjects. The conduct of human-subjects research is a privilege, not a right, Professor Berry observed.

As for overhead and efficiency, Professors Berry and Oakes surmised that it might be more efficient to have reviews conducted through CTSI than in individual departments. It would make judging proposals much more straightforward, Professor Berry commented.

Professor Anderson asked if the IRB turns down proposals not properly reviewed. They do not, but they take more time, Professor Berry said. Currently, the IRB must do what they do not want to do, Professor Oakes said—and they are criticized if they comment on the science, Professor Berry added. But they must do so.

Professor Anderson thanked Professors Berry and Oakes for their report.

3. Update on STAR METRICS

Professor Anderson turned now to Vice President Mulcahy for an update on STAR METRICS (Science and Technology for America's Reinvestment: Measuring the Effects of Research on Innovation, Competitiveness, and Science).

Vice President Mulcahy distributed a significant quantity of material and reviewed the contents with members of the Committee.

- an article from Science, "Measuring the Results of Science Investments"
- an overview of the STAR METRICS program

- a summary of a meeting of AAU senior research officers on STAR METRICS
- a detailed explanation of how STAR METRICS works, time commitments involved for the institutions, the flow of data, what it reports (jobs supported, and by sector and occupation as well as by geographic region. In the next iteration, there will be data on what is supported, what students are being trained in (or not), as well as suggested products from the data. Dr. Mulcahy walked Committee members through visuals of the various websites one can go to in order to review expenditures at institutions and what the data/websites will contain.
- results of federal funding at the University of Minnesota, second quarter, 2011 (from 2,265 awards, 399 vendor jobs, 2,281 FTEs/5,253 individuals on payroll, 340 jobs in institutional support, and 423 jobs at collaborating institutions; other institutional/state data also provided).
- a participant's perspective on STAR METRICS from the U of Texas at Austin.

Vice President Mulcahy offered a number of comments on the handouts; some of the highlights follow.

- The University wants to be at the table when the federal government is discussing metrics. Those who are holding these discussions have a sophisticated understanding of the issues; the concern is that those who receive and use the information from STAR METRICS will not be as sophisticated and could misuse it.
- He had misgivings about STAR METRICS, but after meetings with the National Academies and federal agencies, the take-home message is that institutions need to work collaboratively to get the most out of the system and to prevent its misuse.
- It remains to be seen whether there will be reduced burdens in reporting, as promised.
- There are projected to be three levels of STAR METRICS data; only the first has been tested; it is the one that reports on jobs, vendors, and so on. It is useful information but institutions cannot let research be determined solely by the number of jobs it produces.
- Federal agencies are interested in the data on fields students are being trained in; they want to know if the training experiences align with needs. It is a wonderful question but universities do not train students solely to do a job.
- The second level of STAR METRICS data is to include information on broad categories of impact such as knowledge (publications, citations, etc.), economic effect (patents, spinoffs, etc.), workforce effect (employment, student mobility, etc.), and social effects (health, environment, energy, etc.). These are very difficult impacts to quantify; they are more qualitative. But there are some surrogate measures that people equate with the broad areas of impact. The sponsors understand the difficulty of these assessments; it is not clear that other users of the data will.
- The goal is that there be no new burden on faculty members and only a modest burden on institutions, because STAR METRICS is intended to rely on data that already exist (but not all universities organize data the same way, if at all). What those who have looked at the effort have concluded is that it takes an effort at the outset but then requires a reasonable level of work.

-- The agencies that have agreed to join STAR METRICS cover about 90% of the University's federal research portfolio and 65-70% of the University's total research portfolio.

-- These data could lead to invidious and unjust comparisons (e.g., between research universities); there is also no way that these numbers measure the impact of research (they have emphasized that it is great to have these numbers as a complement to understanding fundamental research). That is one reason the University is involved: So it does not get into a spot where the metrics are a measure of what it does.

Vice President Mulcahy also reported on an effort to try to achieve a federal-government-wide standard for a faculty activity profile, something NIH is pushing heavily. This is being fast-tracked.

Professor Anderson inquired about the concerns about potential users of STAR METRICS data and information. Vice President Mulcahy said that higher education is being questioned as a public good as never before; in efforts to justify what it delivers, he is concerned that those who do not understand the value of research will assume these numbers tell the entire story. For Congress and legislatures facing massive deficits, if they use only these numbers, the outcome might not be positive for higher education. He noted that all of the data are public and that there will be no data on individuals—it will all be aggregated. He also agreed that there is a danger of micromanagement. These are all data already available; some are challenging research purely on the basis of the titles; STAR METRICS makes it possible to go beyond keywords.

Following brief discussion about the source of funding for these projects, potential problems in the standardized CV program for those who have the same name as other people (it may be that the system assigns a unique identifier), and privacy concerns, Professor Anderson thanked Vice President Mulcahy for his report and adjourned the meeting at 3:55.

-- Gary Engstrand

University of Minnesota