

Minutes*

**Senate Research Committee
Monday, September 12, 2011
2:15 - 4:00
238A Morrill Hall**

- Present: Linda Bearinger (chair), Alvaro Alonso, Breanne Byiers, Arlene Carney, Margaret Catambay, Marc Dunham, Demoz Gebre, Maria Gini, Greg Haugstad, Seung-Ho Joo, Frances Lawrenz, Jennifer Linde, Timothy Mulcahy, Christopher Nappa, Kola Okuyemi, LaDora Thompson, Kyla Wahlstrom, Karen Williams, Lynn Zentner
- Absent: Melissa Anderson, Anna Clark, Paul Cleary, Jerry Cohen, Robin Dittman, Tucker LeBien, Federico Ponce de Leon, Thomas Vaughan
- Guests: Peter Radcliffe, Chris Frazier, John Kellogg (Office of Planning and Analysis); Associate Vice President Pamela Webb (Sponsored Projects Administration); Moira Keane (Human Research Protection Program)
- Other: none

[In these minutes: (1) surveys of students; (2) human subjects regulations; (3) Academic Health Center report]

Professor Bearinger convened the meeting at 2:15, asked for introductions, and reviewed the charge to the Committee. She said she would also like to have a discussion about how the Committee dynamic can lead to more timely and effective discussions and decisions. The Committee makes recommendations to the Faculty Consultative Committee, advises the President and senior officers on research matters, evaluates research policies, and speaks for the faculty on matters related to research.

1. Surveys of Students

Professor Bearinger welcomed Drs. Radcliffe and Frazier and Mr. Kellogg to the meeting to discuss surveys of students. She asked the guests to pose issues to which the Committee can respond.

Dr. Radcliffe distributed copies of a handout and reported that this agenda item arose as a result of a discussion among a number of administrative offices about the number of student surveys that are sent out, how students are contacted, and ways in which the surveys might be coordinated. They would like advice from the Committee on surveys of students and how, institutionally, survey activity might be managed—if it should—and how to manage resources and support.

Dr. Radcliffe referred to the language of the handout:

The Office of Planning and Analysis (OPA) supports surveys at the University of Minnesota that involve requests for information from faculty, staff, students, alumni, applicants, and other

* 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.

constituents. Survey planning and sampling for researchable activity are managed through the Office of Planning and Analysis Survey Advisory Team (O-SAT), which includes leaders in the Office of Institutional Research, Office of Measurement Services, and the Office of Planning and Analysis.

Effective Survey Practices

Below are key elements of surveying and sampling that are considered important to the coordination and alignment with University initiatives, academic and administrative goals, and strategic agendas through OPA. Each is followed by a brief summary of the steps taken (and in many cases, still being taken) by O-SAT to address the key elements.

A. Alignment with U's priorities and agendas

Created process for capturing project's purpose and its alignment to the U's strategic goals

B. Appropriate design, timing, mode of delivery

Providing online survey resources and customized support
Making available education resources to the U community (i.e., The Survey Connection, Survey Peer Network)

C. Minimal survey replication

Encouraging collaboration and partnerships on survey projects

D. Minimal survey burden

Calendaring survey projects for reference
Focusing 2011-12 year on sampling issues

E. Results shared

Requesting project plans for sharing results with stakeholders

F. Federal requirements are being met

Drawing greater awareness to HRPP, IRB, Privacy and Data Security

G. U's policies followed

Established review practices of survey and sampling plans
Providing education about the implications of using external software tools

H. Legal risks to the U minimized

Identified procedures (now in place) to identify data privacy and technological risks

I. Best practices followed

Providing multiple expert reviews and advice for survey projects.

Dr. Frazier said that there have been surveys of students for several decades, but the volume has increased because of new technology. In 2009 a group convened (the Survey Advisory Team) from units within the Office of Planning to begin to address the compounding issues and, in particular, the challenges faced for high quality, efficient, and coordinated collection of data from students. Their initial focus was on reviewing and identifying key process and procedures for survey research that led to discussions with the Institutional Review Board (IRB). Communications and education led to greater emphasis on best practices for performing survey research by reaching out to others about this work and survey research practices. The focus had started with students but their work expanded and became applicable, and critically important, to research involving University faculty and staff and also other internal and external communities.

Dr. Frazier reviewed the key efforts they have undertaken:

The **Office of Planning and Analysis** asks for proposed survey and sampling projects to:

- be reviewed to ensure best practices are being implemented,
- determine that University of Minnesota policies and procedures are being followed, and
- make sure that institutional resources are being managed properly by minimizing duplication efforts.

For more information, go to http://www.academic.umn.edu/planning/surveys/form_intro.html

The Survey Peer Network (SPN) is a platform designed to connect University professionals with survey-related resources—and each other. We hope to generate a campus-wide awareness of survey best practice and implementation at the University, and to facilitate survey-related conversation through multiple communication channels. Visit our website at <http://surveys.umn.edu/spn/index.html>.

The Survey Peer Network is kicking off its fall series on Wednesday, September 21 with *Protecting Participants and Ourselves: IRB and Privacy Issues in Survey Research*, a 90-minute session that will provide information about ways to protect participants (and ourselves) while planning, administering, and analyzing survey research. It will focus on IRB, HRPP, privacy, and data security, and provide a foundation for sound, quality research using best practice strategies. This session is geared toward general survey practitioners on campus, as well as those involved in social sciences research; in October, SPN will host a similar session geared towards those in the health sciences.

The Survey Connection is a communications platform designed to connect University of Minnesota professionals with essential survey information and resources. We seek to increase survey literacy and competency in all aspects of University survey use through multiple communication channels. The Survey Connection keeps you connected so you stay informed. Visit our website at <http://surveys.umn.edu/>.

Enterprise-Wide Survey Software Evaluation (ESSE) Committee is a collaborative effort overseen by Senior Vice President for System Academic Administration Robert Jones; ESSE is led by the Office of Planning and Analysis in collaboration with the Office of Information Technology. Representatives from 10 campus-wide units make up the Enterprise-wide Survey Software Evaluation Committee. With extensive input from the campus community, the committee has developed an RFP (released September 9, 2011) and will make a survey software recommendation by Spring 2012. For more information, visit http://www.academic.umn.edu/planning/surveys/esse_updates.html.

The objectives are straightforward:

Gather feedback broadly from the University community to identify survey software requirements for enhanced faculty scholarly collaborations and research, undergraduate and graduate student classroom projects and research, and administrative tools used for programmatic priorities.

Identify a best-practices software tool or suite of tools that will deliver the features and flexibility required to meet the wide-ranging needs.

Make this tool broadly available as a free or low-cost "common good" to enhance academic and administrative excellence, collaboration, security, and cost-effectiveness across the University system.

The problem has been volume, Mr. Kellogg reported. In earlier times surveys were more expensive and complicated; with email, they are very easy to do, and there have been many more of them sent. Many of them have not been good (i.e., good quality). There have been a number of efforts to control the number but this is the first one with legs. This is not an attempt to block surveys, he assured the Committee; it is an effort to administer better surveys and help prevent students from being bombarded with them. (In the past, surveys would receive response rates of 80%; now they might receive 20% and people think that's a good result. They have no idea who is reading the results or whether the information is any good.)

Mr. Kellogg noted that a list of student addresses must be provided to anyone, inside or outside the University. The University can charge \$50 for providing the list, and students do have the option to suppress their address in the University's database. They would like to work with both internal and external groups to be sure that they have useful and valid data when they conduct surveys. They are working on developing a new sampling approach. It is not just surveys, he said; it is also advertisements and requests for participation; they have learned that students have multiple email addresses, so surveys are sent everywhere. They don't know if students even open them.

Professor Bearinger asked if their office has oversight responsibility for other offices that do surveys. Only a few, Dr. Radcliffe said: the Office of Measurement Services, the Office of Institutional Research, and Health Science Research Center (formally in the Academic Health Center, now part of the Office of Measurement Services). They have no direct authority over others, so that limits how much they can control the volume of surveys, and they cannot stop people from using data from surveys, no matter how bad they might be.

Professor Bearinger commented that the ease of doing surveys has generated disadvantages, including the number of surveys students are asked to respond to and the quality of the surveys. There are also IRB issues. These surveys do not necessarily create good measures or outcomes. Dr. Frazier said they are starting to coordinate more with units doing survey work and learning what others are doing. SPN (see the list above) has over 300 members.

Professor Gini expressed surprise that student addresses are public. What makes them so? The Minnesota Data Practices Act, Mr. Kellogg explained, which has been in place since the 1970s. The University must provide the name, address, telephone number, email address, whether a student is full- or part-time, and so on. Many people are shocked to learn that the University cannot withhold that information from anyone who requests it. Professor Joo asked if the private institutions are different in this regard; they are, Mr. Kellogg said. And the law, he added, was written when electronic data were not available. He repeated, in response to a question from Dr. Wahlstrom, that the University must release the data to ANY organization or individual who requests them, with a charge to cover the University's costs. Some buy the list and re-sell it, he said. They agreed on \$50 as the cost to generate the list, but it is a burden on Institutional Research, Dr. Radcliffe commented. And the result is that students receive messages from grocery stores, book stores, dating services, and so on, Mr. Kellogg added.

Is it just state law, Professor Gini asked? It's state law, federal law (FERPA), Regents' policy—a combination platter, Mr. Kellogg said. One can see why the address-suppression requests are much higher for graduate and professional students, Dr. Radcliffe observed.

And there is much more information about faculty and staff available, Mr. Kellogg noted, including salaries. The legislature would have to rewrite the law to increase privacy protection. Professor Gini commented that there is much stronger privacy protection in Europe.

Professor Bearinger asked what questions they have for the Committee. To the extent someone is involved in research with students, Dr. Radcliffe said, it would help if they could coordinate with his office. Much of the survey research at the University is local—in class, perhaps—and while there may not be a large number of students involved in each one, there are huge numbers of such surveys (they were able to identify over 2000 surveys in just a couple of months). Most surveys are invisible to them. If students receive a survey from class, the college, the University, and outside organizations, they tend not to respond to institutional surveys or even look at messages from the University conveying information they need.

Dr. Frazier said the new vendor (see ESSE above) will be able to provide a calendar system that can identify the number of people doing surveys during a week, which will allow someone to choose when to administer a survey. An advantage of a central system is that they can tell who is receiving surveys and they can look at response rates. They can also create a library of survey questions and instruments to help improve quality.

Professor Alonso asked if the surveys require IRB approval. They cannot require it, Dr. Frazier said. The IRB could require someone to communicate with them, Professor Alonso responded. Dr. Frazier agreed and said they do not provide support for projects that require IRB approval but do not seek or comply with IRB requirements. But they want to provide a service that people want to use, Mr. Kellogg said.

Professor Okuyemi asked what niche their office filled in relation to other survey services, such as the one in the Academic Health Center, which has staff who can support longitudinal, sponsored research. Dr. Radcliffe said that they do surveys and provide services for sponsored-research programs in the Office of Measurement Services, but most of their work is administrative support for academic work at this time.

Professor Joo asked how soon their office can provide feedback if asked to conduct a survey. Within three to five days, Dr. Frazier said—and the next day if it is urgent, Mr. Kellogg said. He also said that their office works with people at Morris, and Dr. Frazier added that they work with all campuses.

As for this agenda item, Professor Bearinger reported, Associate Vice President Lawrenz suggested it. Dr. Lawrenz said that Associate Vice President Paulsen, in the Provost's office, had convened a meeting with representatives from a number of offices, and it seemed like a compelling topic especially for this Committee, for faculty members who are doing research. Dr. Carney said she thought it should be brought to the Committee because the subject is important for faculty and staff who do surveys and it is important that they think about the implications of a survey. Faculty members also mentor students who are doing research, and the mentors can make sure that any survey goes through the IRB process, or not, as needed. The question is how to communicate the issues to all units across the institution, Professor Bearinger said.

Dr. Carney said they also hoped that the Committee would help identify appropriate issues and raise them with faculty and staff. Sampling versus mass emails is a significant issue, Dr. Frazier commented. Professor Bearinger said she would bring the issue back to the agenda so the Committee can think about the questions.

There are so many people who could use the services, Dr. Wahlstrom commented, and ask questions of any potential vendor. She asked that they stay engaged with the Committee and keep it updated.

Professor Gini asked if they have any sense of the cost of survey software. Dr. Radcliffe responded that the institution is already spending a lot of money on surveys; what they hope to do is consolidate the funds in order to provide an enterprise-level software that will be cheaper. A number of departments have "junior licenses" from major vendors, Mr. Kellogg reported, and are spending money on those as well.

Dr. Frazier suggested that a member of this Committee could be part of the evaluation of vendors.

Professor Bearinger thanked Drs. Frazier and Radcliffe and Mr. Kellogg for the report and said the Committee would return to the topic.

2. Human Subjects Regulations

Professor Bearinger now welcomed Ms. Keane to the meeting to discuss proposed changes from the (federal) Department of Health and Human Services (HHS) in human-subjects research-protection regulations. (The proposal can be found at <http://www.gpo.gov/fdsys/pkg/FR-2011-07-26/pdf/2011-18792.pdf>) Professor Bearinger noted that over the summer HHS had issued an ANPRM, or "advanced notice of proposed rulemaking," to change the Common Rule

(<http://ori.hhs.gov/education/products/ucla/chapter2/page04b.htm>), which "is a federal policy regarding Human Subjects Protection that applies to 18 Federal agencies and offices. It does not apply to federal agencies that have not signed the agreement (e.g., Department of Labor, etc.). The main elements of the Common Rule include: Requirements for assuring compliance by research institutions[;] Requirements for researchers' obtaining and documenting informed consent[;] Requirements for Institutional Review Board (IRB) membership, function, operations, review of research, and record keeping. The Common Rule includes additional protections for certain vulnerable research subjects." Committee members were provided with the 19 pages from the *Federal Register* with details of the proposed changes.

Ms. Keane said she would talk about what the proposed changes mean for the University. An ANPRM is advance warning that HHS will post proposals. The Common Rule portion of the regulations was started in 1981 and tweaked in 1991, but the substance of the regulations has not changed since the early 1980s. They were put in place just before the Reagan administration took office and were intended to protect human subjects, and a number of the provisions were put in hurriedly.

Ms. Keane said she was glad to see that changes are being proposed but that she has concerns about some elements of the ANPRM. She encourages individuals and groups to respond to the proposed changes. There have already been over 200 comments, and the first ones raised such serious questions that HHS has extended the comment period to allow more. The Office of the Vice President for Research will provide comments on behalf of the University, but she encouraged others to do so as well. A number of national groups are making comments, as are individual researchers. They would all like a dialogue about updating the regulations because this is the first opportunity to have one in many years.

If one is inclined to comment, Ms. Keane advised, one should read the proposal all the way through, because the first parts sound fine—but later parts do not. She noted that there are 74 questions posed in the ANPRM, plus nuances, so over 100 questions in total. She reviewed the major parts of the proposal.

Ensuring Risk-Based Protection: This sounds like a good idea, but later sections of the proposal add significantly cumbersome restrictions for data security which may be a barrier to conducting some research.

Streamlining IRB Review of Multi-Site Studies: Requiring a single or lead IRB review for studies conducted at multiple sites. This applies primarily to clinical trials and would reduce review burden at the local level. Critics suggest that there needs to be some local oversight and control as the University should not be "outsourcing" its ethical oversight of studies.

Improving Informed Consent: The ANPRM talks about process but leaps immediately into documents, which maintains a focus on the legalistic aspect of informed consent documents rather than focusing on the education of the public concerning research participation.

Strengthening Data Protections To Minimize Information Risks: This is about causing harm and relates to the section on risk-based protection. It essentially calls for HIPAA-like rules for behavioral and social-science research, very robust—and some say draconian—standards for data security.

Data Collection To Enhance System Oversight: This is a weak proposal; if one forwards more data, such as adverse events, to a central repository, without context, it is questionable how this would enhance protections. It is vague and unclear.

Extension of Federal Regulations: The regulations would apply to all research, even that conducted without federal funding. The University does apply the rules to all research but it has some latitude, especially with respect to student research. This would require reporting for all research. She would endorse extending the protections to all research but not subjecting all research to the same regulation and oversight, Ms. Keane said.

Clarifying and Harmonizing Regulatory Requirements and Agency Guidance: This is almost throwaway language. 18 federal agencies have agreed to the Common Rule, Ms. Keane said, but they can all embellish it, so there really isn't a Common Rule. But this proposal creates more DISharmony and creates more of a disconnect between agencies.

This ANPRM represents a case of "be careful what you wish for," Ms. Keane concluded. They would like the conversation with the federal government, but there are problems with what is being proposed. More comments mean there will be more attention paid to the proposed changes, so she again encouraged people to comment.

What is good about the proposal, Professor Alonso inquired? Opening the conversation is a good thing, Ms. Keane said. She served on a subcommittee of the Secretary's Advisory Committee on Human Research Protection (SACHRP) to look at the regulations; that subcommittee had 147 recommendations, some of which are included in this ANPRM. They included relaxing review for minimal-risk research, which is very positive; she would argue in favor of more institutional prerogative to identify minimal-risk research and to be more flexible with timelines.

What about the multi-site recommendations, Professor Alonso asked? The proposal is to identify a single site for IRB and scientific review, which would introduce a number of efficiencies, Ms. Keane said. It is unclear what the local obligations would be, and whether institutions would be the lead IRB or whether commercial IRBs would be selected. The process is unclear. There would continue to be local obligations as well as those at the major site and the proposal does not acknowledge the local context issues.

What way does she see the regulations going, Professor Okuyemi asked—towards more regulation or less? Her answer could affect whether more researchers become involved in commenting. This will take a long time, Ms. Keane said, and often there isn't an ANPRM, which is a good sign that there is opportunity to influence the process early. Those who are wise about these processes say this could take two to three years. The University could make a number of comments because it has a considerable amount of research, federally funded and non-funded. Once a comment is made, the agency is required to review it and summarize it and to account for a number of comments in a similar vein.

Associate Vice President Webb agreed that the agency must take all comments into account and must be able to demonstrate to a higher authority why it responded as it did and why it did not follow the recommendations contained in comments. The number of comments does matter, and individual endorsements of statements by a professional association count as another comment.

Professor Bearinger inquired if the Committee could make a comment or an endorsement. It can, both as a committee and its individual members, Ms. Webb said. Ms. Keane said that there probably would not be consensus within the University, which is fine because different groups have different stakes in the outcome. She said that many in the behavioral and social sciences will be in favor of relaxed procedures and may not read later in the proposal about more onerous reporting requirements.

What is the deadline, Professor Bearinger asked? The deadline for electronic comments is October 26 at 5:00 Eastern Time, Ms. Keane said; at that time they turn off the site for comments.

Dr. Wahlstrom asked if any changes would be made wholesale or in separate pieces. They do not know, Ms. Keane said. The approach could be based on the comments; some sections could see no change and some of the changes could fall off the table. They have drafted responses to 39 of the 74 questions, the ones that most affect the University. Vice President Mulcahy said he would be glad to share the response with the Committee, which is being sent on behalf of the University. He also encouraged individuals to respond with comments relevant to their own experience.

Professor Bearinger asked Committee members to volunteer to draft a Committee response to the ANPRM; Professors Alonso and Linde agreed to do so. Ms. Keane said that they should call her if they have questions. The goal, she said, is to make research happen, happen safely, and without a great deal of burden.

Professor Bearinger thanked Ms. Keane for joining the meeting.

3. Academic Health Center Report

Vice President Mulcahy announced that the report from the Academic Health Center Steering Committee is out for comment. The intent is to use the comment period for the expression of community views and the comments will be taken seriously. He encouraged everyone to respond, and while they will not necessarily make every change every comment recommends, if they hear nothing, nothing will change. He asked that comments be submitted by the first week in October. (Comments can be made through <http://blog.lib.umn.edu/ovprcomm/ahcreview/>)

Professor Bearinger noted that Vice Presidents Friedman and Mulcahy had co-chaired the Steering Committee and that it looked at the scope of the AHC and its leadership structure. The Faculty Consultative Committee will be responding formally to the report. She said she would bring to this Committee updates on the FCC deliberations.

Professor Bearinger adjourned the meeting at 3:50.

-- Gary Engstrand