Minutes*

Senate Research Committee
Monday, April 2, 2007
1:15 - 3:00
238A Morrill Hall

Present: Steven Ruggles (chair), Richard Bianco, James Cotter, Dan Dahlberg, Sharon Danes, Donald Dengel, Genevieve Escure, Steven Gantt, Bridget Helwig, Shikha Jain, Paul Johnson, Jennifer Linde, Ellen McKinney, Timothy Mulcahy, Kathryn Olson, Mark Paller, George Trachte, Barbara VanDrasek, Sanford Weisberg, Jean Witson

Absent: Linda Bearinger, Arlene Carney, Robin Dittman, James Luby, Federico Ponce de Leon, Selam Rodriguez, Thomas Schumacher, Virginia Seybold, Charles Spetland, Michael Volna

Guests: Michael Davern (School of Public Health), Robert McMaster (Geography), Alex Rothman (Psychology), Aldo Rustichini (Economics), Chris Uggen (Sociology); Associate Vice President Ed Wink

Other: none

[In these minutes: (1) social sciences infrastructure needs; (2) IRB processes]

1. Social Science Research Infrastructure Needs

Professor Ruggles convened the meeting at 1:20 and welcomed five faculty members from the social sciences to discuss social science infrastructure needs: Professors Michael Davern, Robert McMaster, Alex Rothman, Aldo Rustichini, and Chris Uggen. He said he would like the Committee to have a similar session, before the end of the year, with faculty members from the arts and humanities.

Professor McMaster began by explaining that Geographic Information Science/Systems (GIS/S) is found in many colleges and fields (Natural Resources, Public Health, CLA, HHH, Design) and the research/infrastructure needs differ depending on the approach of the researchers, which tends to focus in two areas: natural science or social sciences/humanistic. There is a need for two large labs for the University to be nationally competitive, one for the social sciences/humanities on the West Bank and another linked to the Institute on the Environment for natural resource analysis. In the case of the West Bank, a lot of synergies could be developed between the Population Center, the Humphrey Institute and Geography, for instance. In its recent strategic plan, the College of Liberal Arts has proposed an initiative on spatial thinking that would likely include a spatial analysis laboratory.

The two labs would tackle different types of research. The social science laboratory might focus on the relationship between transport, housing, poverty, land use, and related social issues. They need a lab with big equipment, servers, and software license packages that researchers would need. There is

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tremendous capacity for the University to move into the forefront of GIS research, but they need labs and technical expertise.

Part of this proposal is in the CLA compact, Professor Ruggles noted; are they working with other colleges? It is part of CLA's planning initiative, Professor McMaster noted again; it is also a compact initiative of five colleges to start the planning process on how to integrate GIS/S on the campus. They will ask for more money in the future, Professor Ruggles asked? It seems likely, Professor McMaster affirmed.

Are these kinds of labs in place at other universities, Professor Dahlberg asked? And if so, how are they supported? Professor McMaster said they do exist at universities strong in geography, such as Kansas, Michigan State, Penn State, and Harvard is now starting one. Most of the labs were started with internal university funding and migrated to external support. Some of the staffing may be provided by the institution.

Professor Ruggles reviewed the history of computational facilities for the social sciences and asked if anyone could speak to research computing. Professor McMaster noted that the social sciences used to rely on Unix-based computing, but that has dwindled away.

Professor Ruggles asked about Research Data Centers. Professor Davern reported that the US Census Bureau has begun granting access to confidential census data in certain place (at major peer institutions). The Research Data Centers are not necessarily computer-intensive but there must be a secure data environment; if they are, they can receive confidential economic household data. Researchers apply to get access to refined data, an important need at the University (especially given the trend on the part of the federal government to release less and less information publicly because of a fear that individuals can be identified). Obtaining a Research Data Center at the University would be very useful.

In addition, Professor Davern said, the Census Bureau is looking at linking census data to health data resources (Medicare, Medicaid), data that will never see the light of day except through a Research Data Center.

The Research Data Center would cost about $200,000 per year, some of which can be recovered. The cost covers Census Bureau personnel who review output data to ensure that no personal data is released. There has been talk about establishing a Research Data Center with Mayo and the Federal Reserve Bank or about the University establishing one alone. Most RDCs at other institutions are not focused on public health data, available through a Data Research Center, and the University could build a niche in research on them.

In response to a query from Professor Johnson, Professor Davern said there are many IRB issues associated with Research Data Center research but that the territory is well-charted; the federal government has updated its regulations regarding data sharing, and the IRB would be review access and use of the data. The data are still under government control; to use them requires one to obtain special sworn status (i.e. becoming a Census Bureau contractor) and essentially become Census Bureau employees in terms of the rules to be followed.

What is the advantage of having a Research Data Center at the University, Professor Weisberg asked? It is cheaper to do research, Professor Davern said; one must travel to other sites to do research

because one must do it on site, one can use no media to duplicate the data, and the Census Bureau watches over the work. There is a constant effort to balance privacy issues and use of the data for good purposes.

Professor Dahlberg interpreted this as the government relaxed the rules and started the centers, and is now clamping down or reversing their position. Professor Ruggles said researchers are worried that "public use data" is drying up because of concerns about confidentiality, so most of the data are only available through Research Data Centers. But that is not the main reason for obtaining one of the centers; the University has the opportunity to become a national leader in research done at the intersection of geography and health; most other centers are dominated by economists.

If a center were on the campus, would it have the same security that exists at the Census Bureau, Professor Dahlberg asked? It would. Who pays for it, he asked? Will there be Census Bureau people on site to watch over the use of the data? If so, who covers that cost? $200,000 seems a modest amount to cover security and personnel. Professor Ruggles surmised the cost would be closer to $300,000, but pointed out that some of it would be recovered. (In response to a question from Dr. Paller, Professor Davern confirmed that the research can link individual data in the databases.)

A researcher who is not an expert in statistics is out of luck or must do all the work if he or she cannot talk to a consultant, Professor Weisberg commented. One brings in a partner, Professor Ruggles said. Why is there not an on-site expert, Professor Weisberg asked? That is more expensive, Professor Davern said, and researchers want control over the data; an on-site person will likely not be as well-trained in analysis of the specific data the researcher is working with.

Professor Rustichini next explained that as part of a CLA-led initiative to support the activities of researchers from economics, psychology, sociology, political science, and other social science departments a behavioral social sciences lab has been opened. The lab has dedicated screens and a central server, needed for experimental research. The lab functions well and is widely used. What is needed for efficient use of the lab is software, technical support staff, and an administrator to run the lab and keep track of experimental subjects. Professor Escure asked who uses the social sciences experimental lab and whether it is open to any faculty members as well as to students doing linguistic or sociolinguistic research. It is, she was told.

Professor Ruggles said that Professor Sullivan in Political Science has also talked about a more ambitious infrastructure in the future that would include MRI machines. Professor Uggen reported that the social science chairs all have problems in recruiting and faculty retention because they see important research topics in the literature but cannot recruit faculty because they lack the necessary labs and equipment to do the research. They have brought in consultants and drafted proposals for a lab that will strengthen disciplinary scholarship and also have an interdisciplinary component. The goal is to strengthen research across the social sciences by building infrastructure.

The University has a world-class fMRI center, Dr. Paller pointed out. Professor Uggen agreed but said that getting time on the machine is difficult and expensive. Professor Rothman said that a new machine cannot be turned on tomorrow; the question is what long-term capacity is needed for success. Psychology has several faculty who are leaders in their field who these facilities. The explosion in the use of brain imaging techniques in psychology has been dramatic over the past ten years and can now be found throughout nearly all areas of psychology. Given the increase in demand, getting enough time can

be a challenge. Some departments of psychology have dealt with this issue by having their own machine (e.g., Dartmouth; USC) and this has enabled them to attract and retain national leaders in this area of research. The economics of research in the social sciences has changed significantly in recent years. In the past, one could envision each faculty person leading their own independent lab with their own personal equipment; now there are tremendous infrastructure needs, driven in part by the steady growth of multi-disciplinary research. Not every department needs its own fMRI and computer lab but needs must be identified. The question is where investments should be made. And the University needs to be sure to recognize that investments in equipment need to go hand in hand with investments in technical support staff.

Access to the fMRI lab is more and more difficult, Professor Rustichini agreed, and the University will need another machine because the one is already at capacity. Not every group needs to learn through its mistakes, he added, citing as examples the learning of brain data analysis that is done independently at the moment in the different labs.

Needs must be met, Dr. Paller agreed; his point was whether there is really need for another 3T magnet (each of which costs about $2.5 million) in another University-wide center disconnected from where the momentum is now. If it were made part of the existing center, it would be updated as needed. But he said that researchers in the social sciences should not be waiting in line to do their work. The cost of the magnet is one thing, Professor Dahlberg commented; long-term maintenance and personnel are another. That is paid for through the use charges, Professor Rustichini said.

The Department of Psychology is also a world leader is psychophysiological research, Professor Rothman said. Thus, there are infrastructure needs in addition to brain imaging machines. There has been some discussing of expanding the behavioral social science research lab in this direction. Again, it's important to note that support staff will be critical as new faculty from across the social sciences start to use these tools. Finally, the department is a leader in behavioral genetics research and careful consideration will need to be given to ensure that the necessary resources are available to sustain this area of strength and to ensure collaboration with relevant faculty in the AHC.

Who coordinates social science research, Professor Johnson asked. Vice President Mulcahy? That is a role his office is beginning to play, Dr. Mulcahy said, it has not done so in the past. They are planning for research ten years from now; the University cannot play catch-up. He said he would like to hear from people such as the individuals at this meeting to help guide decisions. They must be planful because the infrastructure needs are beyond the means of any single college to afford. He helped CLA get the social sciences lab, but imaging technologies are more difficult. Dr. Paller agreed and said there are plans to expand the imaging lab. They must provide the needed capacity through the lab or elsewhere, but there should not be duplication across the campus. If the capacity is not provided, people will leave or do whatever they can to survive.

Professor Johnson commented that he is serving on the budget model subcommittee, which has heard a lot about pressures on the natural sciences for labs and set-ups. These are more big-cost items; where will the money come from? That question must be addressed, Vice President Mulcahy said; set-ups in the social sciences can now be as expensive as those in the natural and medical sciences because they rely on the same technologies. He agreed that the colleges cannot afford these infrastructure costs.

Professor Dahlberg asked the guests if a college could obtain funding for a lab through the compact process. Did they understand the compact process? Professor McMaster said he had an advantage in that he was associate dean of CLA and involved in the compact process, so understands what is going on. He agreed, however, that was probably not true of other department heads (he is chair of Geography). Professor Johnson asked what he thought about the compact process as a mechanism to meet these needs. Professor McMaster said he thought there should be a partnership between the Provost, the college, and the Vice President for Research—all of them need to be at the table. Vice President Mulcahy said that his office is represented at compact discussions and he provides views to the senior vice presidents on research priorities.

Is there any attempt at putting interdisciplinary activities together in their own compact, Dr. Paller asked? There is, Dr. Mulcahy said. The deans have high priorities for their own colleges, and can only choose a few, but there are several good ideas that are not the priority of any one college. The interdisciplinary team lobbied for an interdisciplinary compact; it will be part of the process in the future. They also plan to develop a suggested list of critical research infrastructure needs based on the compacts: if the University is to be competitive in X field, these infrastructure items must be funded. There are also funding mechanisms outside the compact process, Dr. Mulcahy observed.

If the resources are not there, Professor Rothman commented, the University won't be able to attract faculty and those who are here will leave for other institutions. In places where the University has been fortunate with its investments in infrastructure, the constituents are there to use it and advocate for it. In other areas, where the University has not yet made critical investments, there is silence. Dr. Mulcahy agreed. He said he is mailing information to the faculty and staff about the Research and Scholarship Advisory Committee that he is appointing, a group of senior faculty and staff representing research across the campus. The first charge to the group will be to develop a strategic plan. He agreed the University cannot afford to lose strengths it already has, and beyond that it must decide where to invest money—and must be sure it invests in long-term needs. Issues come to him that he is not completely knowledgeable about so he wishes to have the committee advise him.

Undergraduate research is also important, Professor Escure said; are the labs open to undergraduates (who cannot afford to pay a lot, who may be doing individual research or senior projects)? Undergraduate honors thesis research is being done in the lab, Professor Rothman said; more broadly, undergraduates are actively involved in research in the psychology department. To date, faculty typically cove the costs associated with undergraduates doing research. Dr. Mulcahy said that Vice Provost Swan, who has responsibility for undergraduate research, is dealing with a number of issues, including increasing research opportunities for all undergraduates, not just honors students.

Professor Ruggles thanked the five guests for joining the meeting.

2. IRB Processes

Professor Ruggles turned next to Assistant Vice President Bianco to discuss proposed changes in the IRB process.

Mr. Bianco distributed copies of a set of slides and observed that there has been long-standing concern about IRB processes in both the social sciences and the medical sciences. They are engaged in a transformation of the medical IRBs, the elements of which he presented at a national conference.

The IRB is independent from the University; the staff, however, determines how the University does things in the IRB process. He is responsible for the safety of, well-being of, and adherence to regulations for all human and animal research subjects—and also for the safety of employees. There has recently been pressure to use a commercial IRB (often composed of retired physicians who can provide a quick turnaround). The University is not looking for a quick turnaround, Mr. Bianco said, it is looking for a local connection.

Mr. Bianco reviewed the University's IRB model: seven panels of IRB members, a total of 80 members, with four medical panels and two social science panels (one for students), and an executive panel that makes policy decisions. Each panel meets once per month; panel members have a range of experience. Of the 37 medical panel members, 21 have less than 4 years of experience, and 9 have less than a year of experience, so there are a lot of new members. The challenges to the University are that there is an increasingly complex portfolio of submissions, an increasing number of clinical trials, increasing demands on faculty time to produce clinical revenue, decreasing availability of experienced IRB members, ongoing turnaround-time pressures, and standards for re-review (stipulations) are more stringent (leading to repeat rounds of review). But the goal is to be a top-three university, Mr. Bianco pointed out; the IRB process is infrastructure and it must be ready to respond to demand. Right now, however, the system could not handle the proposed increase in the number of clinical trials to be conducted because of the demands on volunteer faculty who are also under pressure to increase see patients and increase clinical revenue.

The result is that the 40-year-old model is not nimble enough, the experienced reviewers are overworked and morale suffers, there are increasing pressures to outsource IRB work, and the University needs to emulate its competition, which appears to be more efficient. The proposal they have developed is to change the model for a two-year trial period. They propose to develop an IRB composed of seasoned individuals who are primarily research physicians, they will have an extensive roster of alternates (who will be members-in-training), there will be weekly meetings, the members will receive financial augmentation based on attendance, and they will receive credit for service in annual reviews.

At the same time, Mr. Bianco said, they will continue to develop professional administrative staff, develop and embrace electronic tools, develop and enhance cooperation with other accredited IRBs, and contract for external assessment of program efficiencies. For example, the University has affiliations with the Vet Hospital, Regions, and Hennepin County Medical Center; in the future, the IRB that will deal with proposals will be the one at the institution where the work will take place, rather than both there and at the University.

There will no longer be four medical panels, there sill be one "expert panel" of nine experienced, well-trained members, with a "deep bench" of alternates for changing expertise and availability. This IRB will focus primarily on subjects protection, although it must also do a scientific review if no one else does. They will split off the scientific review from the human subjects protection. Dr. Paller reported that the AHC associate deans have suggested appropriate criteria for peer scientific review; for department-funded research, three individuals should read the protocol and determine if it is acceptable (they must be individuals who have no conflict of interest with the proposed research). That will mean the protocols will not have to be reviewed repeatedly; the proposals will still go to the IRB for human subjects protection, ethics, and safety reviews. Dr. Mulcahy wondered if units have the capacity to provide this review so that it does not become a logjam. They are talking with department heads and

existing committees, Dr. Paller said, and it may be a problem, but the big departments are reinstituting scientific review, and it is not difficult to meet the criteria the associate deans have established. The departments and divisions will do the reviews as they are able; the associate deans will store the records and the questions/answers so that there is an audit trail for adequate peer review.

Professor Johnson said he has been through this process; what is puzzling is that there is local review when there is no national review. Do the different levels mean that research reviewed at the national level is excellent while research reviewed in the department is adequate but not excellent? That is up to faculty peers in the department, Dr. Paller said. The research is not good enough to get a government grant but it is adequate for local funding, Professor Johnson asked? That is fine, Dr. Paller said. If one is on the panel, might one say the research does not meet the standard for first-class science, Professor Johnson asked? It must meet the standard for use of human subjects in research, Dr. Paller said. Professor Johnson said he commended the approach Mr. Bianco has laid out but worries how it will work out. The IRB will still review the proposals after the department review for scientific merit, Mr. Bianco observed.

Professor Linde inquired how far out one must go to avoid conflict of interest in department panel members; in some cases, one knows everyone in the department. As long as they are not co-investigators on the project, they can serve on a review panel, Dr. Paller said, and the department can usually provide a better scientific review than an IRB. Mr. Bianco said the department will have to look at conflict of interest; he noted that IRB review will be required but that conflict-of-interest is a self-disclosure system within the department; it is up to those in the department. One can send proposals to another department, if they are willing to review it, Dr. Paller said; the point is that there is appropriately-constituted peer review. Small departments will probably not be able to conduct such review within the department.

What is very important is that people not reject the idea of working with a central IRB, Mr. Bianco told the Committee. A central committee can review more proposals more efficiently, and if the process works, they will adopt it for the social sciences as well.

This will be the first time that IRB members will be paid, but it is necessary, he said. The University cannot ask for that much faculty time. In response to a query from Professor Dahlberg, Mr. Bianco said they expect that the IRB members will need to devote two hours to meetings once per week and about six more hours in reviewing proposals, so about 8 hours per week. They will go by the NIH salary cap and are trying to figure out percentage of effort.

Will this be part of their job or overload, Mr. Wink asked? The department chairs want it as an offset, Mr. Bianco said. So about 20% of their effort, if 8 hours, Mr. Wink said. Professor Ruggles asked if it would be a percentage of the cap. Mr. Wink said that could be a problem; if there are different salary standards for historians and neurosurgeons, they will be valued at different levels for IRB service. The salary cap is $186,000; will everyone be valued at the same level? Mr. Bianco said that needs to be worked out. If it is effort, the University must pay whatever the person's salary is, Professor Ruggles maintained.

Mr. Bianco said that it may be difficult to explain why the University is paying committee members, but this panel is responsible for preventing people from being killed. They cannot take

clinicians out of a clinic for that long a time and not compensate the department. He said he believes in volunteer work in the University, but this is different.

Most applications are sent back for revisions, which suggests there is a problem, Professor Ruggles commented; either the faculty are really dense or IRBs are not consistent. This proposal will help to address that problem, Mr. Bianco said, because there are always a lot of questions about the science and about the use of statistics.

This proposal will not affect consulting, Mr. Bianco said.

Professor Escure said that it is possible to save more time because it is difficult even to fill out the form requesting exempt status. Many things that cause controversy in the social sciences need not be submitted to the IRB at all, Mr. Bianco said, and he has a consultative committee to develop "smart" forms because they want the IRB to be efficient and fast.

Ms. Witson observed that it appears the changes have been made already. Mr. Bianco said it is in effect and said there will not be a backlog of proposals. He has hired additional staff and if there are questions about a proposal, they will get back to the researcher the next week. He noted that the longest delay in the IRB process is waiting to hear from the faculty member in response to questions from the IRB. He also said that the IRB would not wait on peer review to conduct its review; the IRB will review a proposal that has been submitted to a funding agency whether or not the decision has been made to fund it—and the IRB will not review the science if the proposal has been peer-reviewed.

Professor Ruggles thanked Mr. Bianco for his presentation and adjourned the meeting at 2:55.

-- Gary Engstrand

University of Minnesota