Minutes*

Senate Research Committee
Monday, December 9, 2013
2:00 - 4:00
238A Morrill Hall

Present: Maria Gini (chair), J. Michael Autry, Jeanette Gundel, Daniel Habchi, Goran Hellekant, Philip Herold, Brian Johnston, Seung-Ho Joo, Frances Lawrenz, Amanda Maxwell, Scott McIvor, Kathleen Thomas, Kyla Wahlstrom, Joel Waldfogel

Absent: John Bischof, Arlene Carney, Jayne Fulkerson, Brian Herman, Michael Kyba, Tucker LeBien, Hinh Ly, Richard Nho, Suzanne Paulson, James Orf, Emily Saunoi-Sandgren, Michael Schmitt, LaDora Thompson, Thomas Vaughan, Lynn Zentner

Guests: Channing Riggs (Director, Federal Relations); Debra Dykhuis, Patrice Webster (Human Subjects Protection Program)

Other: none

[In these minutes: (1) Research Animal Resources study; (2) update on federal issues; (3) IRB Exempt status; (4) review of studies without peer review that involve more than minimal risk]

1. Research Animal Resources (RAR) Study

Professor Gini convened the meeting at 2:00 and turned to Associate Vice President Lawrenz to start a discussion of the study of Research Animal Resources (RAR).

Dr. Lawrenz explained that the Office of the Vice President for Research commissioned the study to look at RAR; the organization that conducted the study did both interviews and a survey. The report was very positive and found no serious problems, although there are improvements that can be made and RAR is moving forward on the recommendations.

Professor Hellekant said that the information provided to the Committee from the report seemed to have little to do with the survey that solicited the views of people working with RAR. Dr. Lawrenz said that the survey was only a small part of the report of the external visitors; they interviewed users, talked with the Institutional Animal Care and Use Committee, and visited facilities. Is there a difference between the survey and what is in the report? Professor Hellekant thought so and noted several survey questions that he said were poorly constructed or that did not provide useful information from users. Dr. Wahlstrom agreed that at least one of the questions was poorly worded. Professor Hellekant maintained that the survey did not allow information that would improve the situation for researchers working with animals—which is something this Committee should be concerned about, as is Vice President Herman. As a veterinarian who has worked with animals for about 40 years, he said he appreciated the survey but it does not address user needs and that the people responsible for it did not know what people are using animals for research for. He suggested that this Committee request or create an ad hoc committee, in

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collaboration with the Vice President for Research, to discuss the survey and what can be done to improve the situation for people who use animals in research.

Professor Gini said the Committee was not informed about the history of the survey and who conducted it. Dr. Lawrenz said it was conducted by an external group and the Office of the Vice President for Research had nothing to do with the survey design. She repeated the point that the survey was only one part of the report, which was prepared by a group that looks at animal-care sites. She explained the background of the study and that it found that RAR adheres to federal regulations; Dr. Gillett, the director of RAR, tries to conform fully to the law while also not over-regulating. The responses to the survey, she observed, were very positive. Professor Hellekant maintained it was not well constructed so could not provide useful information.

Professor Gini pointed out that the survey was done and can't be changed. She asked if the Committee wished to do anything at this point. Professor Hellekant said he would like to know how users perceive IACUC and a comparison of federal and state regulations with those imposed by the University and IACUC. Why is it necessary to have five committees inspect animal facilities and use? For many years the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC, seen as the Holy Grail) did not accredit Wisconsin, which nonetheless continued to do animal research. Is AAALAC worth the money? It is not just a problem with IACUC, it is generally true with the use of animals in research at the University.

Professor Thomas said that Professor Hellekant was raising a number of large issues, such as how IACUC and the University work together, which are not within the purview of this Committee. Professor Hellekant disagreed and said the reason for the Committee is to improve the situation in research at the University and urged that a survey of animal users be conducted. Dr. Lawrenz pointed out again that there is an entire report, part of which includes the survey. She said the Committee might have a discussion with Dr. Gillett.

Professor Gini suggested that she and Professor Hellekant and Associate Vice President Lawrenz meet later to decide what the next steps should be.

2. Update on Federal Issues

Professor Gini welcomed Ms. Riggs to the meeting to discuss events in Washington related to research. Ms. Riggs asked that the discussion be off the record; the Committee concurred. She discussed the effects of sequestration (her office needs examples of its effects) and the difficulty of obtaining grant funding. [Subsequent to the meeting, Ms. Riggs observed that because of the budget agreement reached by Congress, much of what she had told the Committee had been rendered moot.]

Professor Hellekant observed that it is a tremendous national waste when 9 of 10 grants are not funded; one is writing novels for the wastebasket when preparing most grant applications. Professor Gini said that that has been the situation for a number of years and that grant success rates varies by agency.

Professor Gini thanked Ms. Riggs for her report.

3. IRB Exempt Status

Professor Gini welcomed Msses. Dykhuis and Webster from the Human Research Protection Program (HRPP) to the meeting to talk about two topics, one of them the process for determining IRB exempt status. She recalled that Professor Konstan had suggested that determination of exempt status be made at the local level, with appropriate training for making the judgment.

Ms. Dykhuis reported that data from the last five years on the number of proposals, requests for exemption, and time completion show a significant improvement in the process. They are required to report the number of exempt studies and time to determination to their accrediting body; the time dropped from 20 days (1215 proposals in 2009) to less than 8 days (883 proposals in 2013).

Professor Gini asked if either of the guests had any intuition on why the number of proposals had dropped so much between 2009 and 2013. Ms. Webster said it may have been because during that period the IRB refined its interpretation of the definition of human subjects research and what requires IRB review. Researchers are provided with information on the IRB website to help them determine if their project meets the definition of human subjects research and would therefore require IRB review. If people are still unsure, as many are, or have questions, or want documentation, they can fill out a determination form, and their office (HRPP) will respond within 3 days on whether the proposal is (or is not) human subjects research. [The determination form can be found at http://www.research.umn.edu/irb/research.html and the link to the form is at the bottom of the site.]

Professor Hellekant asked about the number of requests for exemption and the number approved; those data were not available at the meeting. He said he believes the IRB has increased its stringency and does not allow research that was previously permitted. So either there has been a change in attitude or an unwillingness to accept very minor risk. It is important to know how many proposals were considered.

Professor McIvor asked how they are trying to help people work with human subjects and clarify exempt status. Ms. Webster said they are doing so at two levels. One is whether the proposal meets the definition of human subjects research, and if so, what level of review is required. "Exempt" does not mean exempt from review. If a proposal meets the definition of human subjects research, then a decision must be made whether it falls in an exempt category. If not, then the proposal moves to a higher level of review. Professor McIvor recalled research using human cells and found that it had to be called human subjects research, even though no individual could be identified, even if it was exempt. This can be a complex issue and people may need assistance in interpreting the guidelines.

Professor Gini said she brought up this topic because people who do not do human subjects research, and do not even think of it, nonetheless must be careful because it is a tricky matter. The question is whether people need to go through the process of filling out the form, a question of time and cost. Some say the system isn't broken and doesn't need to be fixed; others say it could be more efficient, which is why the Committee was interested in the data and amount of work involved. Could the process be more distributed? Someone would still need to make a decision about whether a proposal was exempt or not, and might go through training but still not understand everything necessary. Generally, if there are no humans involved, it is not human subjects research, but what about students who develop a new app and want a few friends to try it out—do they need to file with the IRB? Professor Gini surmised that the vast majority of students in computer science have no idea that there is an IRB or rules governing human

subjects research. What about a small class project where students must go to 3 friends to try out an interface?

Ms. Dykhuis said that what they try to do is bring more formality to the process and encourage its use; people are not required to submit proposals to the IRB that do not involve human subjects. The determination form helps people determine if they can undertake their research without IRB review. If they submit the form, their office will let people know very quickly. The form asks questions that help people determine if their proposal meets the definition of human subjects research. It is designed to be an educational tool, Ms. Webster added, and help students think about the issues. They have processed 141 of the forms since August.

Dr. Lawrenz said the process is quick and easy. She said she has used it twice and needed to have affirmation that a proposal did not need IRB review in order to receive an NSF grant. She also uses the form with her classes to help them understand what they must do—it provides a good training moment.

The difficulty is for people who rarely do human subjects research, Professor Gini said. She gives the determination form to students, and asks them to fill it out. If the research is not about human subjects, does she send the form in? Or do nothing more? Ms. Dykhuis said that Professor Gini would have to submit the form to receive an answer about whether or not the research is exempt.

Professor Waldfogel noted that the determination form has binary responses; it could provide answers so that someone filling it out would know if the research is exempt. If IRB review is required, one must submit one of two application forms with complicated questions, Ms. Dykhuis said; the determination form is only to help someone decide if their project meets the definition of human subjects research. If they know their research is human subjects research, they can proceed immediately to submit an application for IRB review.

If research is exempt, do researchers still need to use a consent form, Professor Gini asked? The answer depends on the category of exempt, Ms. Webster said. Some exempt research still requires use of a consent form, but they try to waive consent when they can and still remain within regulatory boundaries.

Professor Gini commented that there are many fine lines in this area and it is commendable that the IRB office can handle them. She said she would not want to do so. But she asked what the cost is to deal with the requests for exemption. If they received zero requests for exemption, what percentage of their work would be saved? Ms. Dykhuis said it takes about 15-30 minutes to review a proposal and reach a conclusion, and the people doing the work are paid about $20 per hour.

Professor Gini asked if the Committee wished to recommend anything be changed.

Professor Hellekant asked if there is any appeal if someone is turned down in a request for exemption. There is an appeal process in place, Ms. Webster said, if someone's proposal is determined to be human subjects research, is submitted, and denied. The case would be reviewed by the full IRB, and that decision can be appealed. Professor Hellekant said there could be a hearing or a separate group to review the decision. If there is a process, it should be public—and it would be valuable if this Committee knew about it.

Professor Gini asked Dr. Lawrenz how broad a protocol must be for a class—one for each class? That is correct, Dr. Lawrenz said.

4. Review of Studies Without Peer Review That Involve More than Minimal Risk

The second topic for discussion was studies involving human subjects that are not peer-reviewed but that involve more than minimal risk to the subjects. Professor Gini asked what the process is and if it was working. Are there issues?

Ms. Dykhuis said the process had not changed since the last time she spoke to the Committee about it. There are four options to obtain a scientific assessment of a research proposal: assessment by the HRPP office (between August and October they made 14 such assessments); by a federal funding agency (where the vast majority occur); by a nationally based non-federal funding agency, or via locally constituted mechanisms using peer review (i.e. departmental peer review, Cancer Protocol Review Committee). On average it takes her office about 20 days to complete an assessment, and she said that she believes the process is working smoothly.

Ms. Webster noted that the HRPP-administered review process is all online and no committee meets; members of the scientific community serve as reviewers. They send proposals to reviewers quickly; sometimes there can be delays in getting responses.

Professor McIvor asked if proposals frequently involve children. Those must meet a higher bar. Ms. Webster said that the regulations do allow more-than-minimal-risk research with children but it requires review.

Professor Gini observed that any proposal without peer review that includes human subjects and more-than-minimal risk cannot be exempt. She thanked Msses. Dykhuis and Webster for joining the meeting, and adjourned it at 3:40.

-- Gary Engstrand

University of Minnesota