

Minutes*

**Senate Research Committee
Monday, January 22, 2001
1:30 - 3:00
238A Morrill Hall**

Present: David Hamilton (chair), Victor Bloomfield, Daniel Brewer, Robin Dittman, Eric Klinger, Leonard Kuhi, Mark Paller, Scott McConnell, Richard Poppele, Barbara Van Drasek

Regrets: Melissa Anderson, Esam El-Fakahany, Phillip Larsen, Sharon Neet

Absent: Susan Miller

Guests: Susan Berry, Richard Bianco, Moira Keane, Thomas Molitor, Barbara Shields

[In these minutes: (1) use of animal and human subjects in research and review of proposals by IRB, IACUC and intersection with academic freedom; (2) the influence of outside (private sector) funding on University research ("The Kept University"), draft statement on; (3) Intellectual Property Policy acknowledgement statement]

1. Use of Subjects in Research

Professor Hamilton convened the meeting at 1:30 and, noting the large number of guests at the table, called for a round of introductions.

He then reported that when the December minutes of the Committee were circulated, Mr. Bianco contacted him and asked that a group of people (the guests at this meeting, all heavily involved in the use of subjects in research) be permitted to attend the next meeting to provide clarification on the use of human and animal subjects in research. Professor Hamilton said he welcomed them. Mr. Bianco provided materials which were distributed to the Committee in advance of the meeting; they are appended to these minutes. They also requested that a note be inserted in the December minutes indicating that the topic arose again at the January meeting and clarifying materials distributed. Professor Hamilton said he would, if there were no objection, direct that the documents be included with these minutes and the note inserted in the December minutes. There was no objection.

[Note: the statement in the December minutes, the focus of this discussion, was as follows:

[Begin excerpt]

It was agreed that evaluation of scientific merit by bodies appointed specifically for the protection of human or animal subjects is appropriate only when a proposal has not already undergone a formal review by qualified peers. In the absence of qualified peer review, the following further considerations should apply:

* These minutes reflect discussion and debate at a meeting of a committee of the University of Minnesota Senate or Twin Cities Campus Assembly; none of the comments, conclusions, or actions reported in these minutes represent the views of, nor are they binding on, the Senate or Assembly, the Administration, or the Board of Regents.

In the case of human subjects, merit review is appropriate if the proposed procedures are such that there is a foreseeable nonzero risk of significant physical or mental harm for any individual subject or if, statistically, such harm from the proposed procedures is known to occur more often than with exceeding rarity.

In the case of animal subjects, procedures that inflict pain or suffering warrant merit review. Simple use and painless killing do not warrant merit review if the animals are reared and bred specifically for research use.

In the case of higher animals or animals not bred for research use, suffering includes social and physical constraints that significantly interfere with normal species-specific patterns of behavior.

There was a difference of opinion regarding whether merit review, when indicated, must be performed by bodies from outside the University of Minnesota.

None of the exemptions from merit review recommended above would alter current policies regarding reviews focussed on protections for human or animal subjects.
[End excerpt]

Professor Berry then explained that she thought it would be helpful if the Committee heard from the faculty committee, the Internal Review Board (hereinafter IRB), charged with protection of human subjects in research. She noted that the committee she chairs is not parallel to other governance committees in that the IRB is established by federal regulation and has responsibilities established in law. The responsibility of the IRB is provide assurance to the federal government that research conducted at the University using human subjects will follow applicable rules (whether or not the research has federal funding). The committee is involved in reviewing ANY research, on any campus or at Fairview (it also serves as the Fairview IRB), that uses human subjects. It is their job to protect the subjects and must look at the risk to the subjects with regard to scientific merit. Dr. Berry said they recognize there could be a conflict between assessment of scientific merit and protection of subjects but they try to assess risk. She explained that federal regulations include an expectation that an evaluation of scientific merit is necessary as it pertains to risk to subjects. For example, if the design of a study does not allow a valid conclusion to be ultimately drawn, then the risk occurs for subjects without any potential conclusion from a study. So the committee assesses scientific merit IN THE CONTEXT of whether study design affects risk to subjects.

Professor Molitor said that the same thing is true for the Institutional Animal Care and Use Committee (IACUC). It is also established by federal statute and, by law, includes both University and external members, the latter of whom are not necessarily involved in research. The role of IACUC is to protect animal subjects; scientific merit is reviewed, especially with respect to duplication of previous experiments and experimental design.

Professor Berry noted, with respect to the letter sent to the Committee (the one appended to these minutes), that it was signed by the institutional officials (Mr. Bianco and Vice President Maziar) charged to be sure the University adheres to its agreements with the federal government--and on which agreement federal funds are contingent. They provided the information in the documents and sent it to the Committee with the blessing of both the IRB and IACUC.

What part of the December minutes are in question, Professor Klinger asked? The report of the subgroup proposing restrictions to be placed on the IRB and IACUC in reviewing scientific merit, Professor Molitor said. Moving beyond the issue of evaluating scientific merit of research, discussion also touched on a remark Professor Klinger had made in the previous meeting regarding the exemption of teaching activities from IRB and IACUC control. Professor Klinger responded that he had submitted a clarification but that the minutes were not amended; in it he said:

"In regard to my statement that IRB and IACUC do not exercise jurisdiction over teaching, what I had meant to say was that the IRB does not review whatever an instructor may do with his/her class for instructional purposes. If I think that my intro psychology class would benefit from filling out a questionnaire on their own motivational structure, just for their own individual edification, I don't have to apply to the IRB for that unless I also plan to use the data for research purposes. As soon as we recruit other students (not in my class), even though for instructional purposes, that does, of course, require an application to the IRB. (I am less familiar with the IACUC role in this and hadn't actually intended to include it in my remark.)"

If an instructor chooses to do something with a class that is purely educational and that involves no outside research at all, the instructor has the latitude to assign whatever he or she wishes (with the obvious caveat that one does not harm the students). The IRB reach should not include teaching, he said.

Dr. Bloomfield, reciting from the document provided to the Committee, noted that "the federal regulations on animal welfare apply to all research, testing and teaching procedures using laboratory animals." Teaching is explicitly included, he pointed out. That is because of the care and use regulations, Professor Klinger said; the IACUC should not try to evaluate curricula. They evaluate the care of animals, not the education, Professor Poppele said.

The IRB does not review what happens in classrooms, Ms. Keane agreed, nor does it look at student evaluations. It does, however, examine "research methods" courses when the students are assigned research outside the class as part of the learning process. Professor Klinger said he understood; his point was that it is not involved when it is ONLY the students in the class who conduct exercises within the class for instructional purposes. Ms. Keane said the IRB would probably not know of such exercises but it would encourage instructors to know the rules governing the conduct of research; the IRB should know of anything conducted outside the classroom.

Professor Hamilton said that his experience has shown that the animal review committee at times does not pay close attention to scientific merit and has sometimes made suggestions that compromised scientific merit; researchers have to accommodate themselves to the suggestions. The University needs to develop a mechanism to inform researchers about the proper role of the IRB and IACUC.

Professor McConnell said he appreciated the time and effort that were put in to the responses to the Committee; they educated him, he said. One concern he has, however, is the "who's in charge here" approach; the opportunity for a collegial approach to the process may have been lost. He suggested that while the IRB and IACUC have substantial authority, they also are intended to reflect local exigencies and standards (within the requirements of their operation). It appears that there are a number of related, important issues--for instance, how "scientific merit" should be evaluated, or how the IRB or IACUC

interacts with individual investigators--that warrant further discussion, and he hoped that the IRB and IACUC, perhaps with this Committee, would facilitate those discussions.

Professor Berry said she agreed completely. The members of the IRB and IACUC are both peers and researchers as well, she said, and they must separate operational difficulties from the reason they exist. There is more they can do to be more user-friendly, she agreed, and they could interact more in order to be a more effective body that encourages researchers to contact the committees. They have taken the position that when there is a "transgression," there is a need for more education rather than concluding that someone is a bad person. Their first obligation is the protection of subjects, she said, but their second obligation is to protect research so that people do good research and the system works well. Professor Molitor said the same is true for the IACUC.

Professor McConnell said he was still concerned about the sweep of the standards for review that the two committees are charged to use. Professor Berry said that is a separate issue that should be taken up at another time. Professor McConnell was concerned that the committee may not be the most appropriate forum for assessment of scientific merit. Professor Berry agreed, in the sense that her committee is not constituted to be expert peer reviewers of the science involved in a given project. Thus, other peer review could be encouraged for proposals (for example, from students) that would improve their scientific merit, making it easier for the IRB/IACUC to assess. Their charge is to assess merit IN THE CONTEXT of risk to subjects, so when other review has taken place this makes the committee's job more straightforward--but it still has to assess scientific merit in that specific arena. The Senate Research Committee could certainly consider if there should be alternative forums for review, but this is a separate issue from IRB/IACUC's charge to assess merit in terms of risk to subjects.

Professor Poppele said there should be more discussion about academic freedom. Evaluation of scientific merit could include many things. The collegial organization of the institution must be kept in mind and the opportunity to turn out academic work in an ethical manner must be maximized.

Professor Klinger said he was reassured by the discussion. The subgroup submitted its report intending that it serve as the basis of discussion; it was not thought to be a finished document. They knew it was a contentious issue and they were charged to draft language to focus the discussion. They tried to make it as precise and as consistent with the regulations as they could but knew it was not finished. The academic freedom issue is a real one, he maintained. It is wonderful to have a collegial university that is supportive but one must be sure it does not squelch ideas that are not shared and that some may think ridiculous because that would chill unconventional thinking and harm academic freedom. Nothing in the draft statement was intended to reduce protection of subjects from harm; if there is any significant risk of harm a proposal needs collegial oversight. One can argue, however, that if subjects are fully informed, one should be able to go ahead with research even if some think it silly.

While she is a strong believer in academic freedom as essential to the academic enterprise, Professor Berry said, academic freedom is trumped by the idea that there is no fundamental right to conduct research using human subjects. Academic freedom in those cases may be second to consideration of research subjects.

Professor Klinger said he disagreed in part. In a free country there is a right to consensual relationships if there is mutual agreement and full disclosure; he said he was not sure there was an institutional right to interfere in those relationships. He said he agreed that research subjects must be

protected from harm but one must be careful not to infringe on the right of free people to arrangements that may include a degree of risk if there is full information. Without that, academic freedom is dead. Those who rely on human subjects research to reveal new information can close off their inquiries. He said he believed there is a right to conduct such research.

Professor Berry flatly disagreed and noted that the University was in court over this issue and asserted the right to protect research subjects. She said there is no due process right to conduct such research and turned to Ms. Shiels to elaborate.

Ms. Shiels explained that there had been a case involving a University researcher in federal court in 1994 and again in 1996 (the same individual was involved in both cases). In 1994 the researcher sought to prevent the IRB from investigating alleged wrong-doing; the court ruled the researcher could not stop the IRB. In 1996 the researcher was suspended and went to court and said his rights had been violated; the court disagreed, said the University had followed the correct process, and also held that there is no fundamental right to conduct research involving human subjects. The court's ruling was based partly on the overlay of federal regulations protecting the interests of human subjects.

Pitting academic freedom against human subject protection is not necessary, Ms. Shiels said. Academic freedom and subject protection function compatibly and those charged with the protection of research subjects do not have as a goal interference with academic freedom; they support research. The goal is to help conduct sound research for the betterment of society. One can say that subject protection "trumps" academic freedom, Ms. Shiels commented, but that is not necessarily a useful approach. If a question arises about a proposal, in terms of scientific merit versus subject protection, the committees will work with the researcher to try to resolve the conflict.

The idea is not to keep someone from doing their work, Professor Berry agreed, but to encourage people to design research that meets the University's goals.

Professor Hamilton said these issues revolve around PROCESS; the issues that were raised with the Committee have been clarified, he said. It now better understands the role of the IRB and IACUC. He has learned one lesson, he said, and that is never again to bring such issues to the Committee without representatives from the IRB and IACUC present to help clarify things.

The purpose of the draft statement, Professor Klinger said, was to try to set boundaries as a way to influence the process of review and create an awareness of problems. The University could benefit from a statement on boundaries that is more explicit in order to sensitize committees (IRB and IACUC) and avoid infringement on academic freedom. He said he agreed that there is no inevitable conflict between academic freedom and protection of research subjects--but there has been infringement on academic freedom in the past because there has not been a clear enough statement on boundaries.

Professor Kuhl said a little common sense is needed; the documents provided to the Committee clarify a lot of issues. The boundaries will be fuzzy and to try to set them in stone is not possible, he asserted; if there is a problem with a proposal, it needs to be addressed, but to try to set the boundaries in policy asks for trouble.

Professor Hamilton noted that in the letter to the Committee Mr. Bianco and Vice President Maziar asked that the Committee withdraw the proposed statement presented at the December meeting.

The Committee has had its additional discussion of the draft statement, Dr. Paller said: it has been today, at this meeting. He moved that there be no more discussion of the statement.

Professor Klinger disagreed and said there should be more discussion. Not to have it means the University is left with the status quo, which is unsatisfactory to many PIs. Professor Hamilton said he would prefer to address in a different and less confrontational way the issues that cause dismay to PIs. Mr. Bianco said the subjects protection program wants to respond to specific process issues but has not had the chance to do so; he said this was not the right forum in which to do so. Professor Hamilton agreed and said the Committee should participate AFTER there have been discussions.

Professor Hamilton asked if the Committee wished to vote on Dr. Paller's motion. He added that to vote in favor of it was NOT to discontinue discussion of the issues that have been raised. Professor Klinger said the motion was unnecessary since the draft statement was not up for action. Ms. Shiels pointed out that the request from Mr. Bianco and Dr. Maziar is that the statement be withdrawn from further consideration and never brought up for a vote. Mr. Bianco said the minutes of the December meeting were very good--but that some of the statements in them could put the University at odds with federal regulations.

Professor McConnell said that the intent is to move forward and that a good foundation has been laid for future discussions. He said he did not want things taken out of minutes, however, and for the Committee to pretend they did not happen. That will not occur, Professor Hamilton assured him.

The Committee voted 6-0, with 2 abstentions, in favor of Dr. Paller's motion.

Professor Berry thanked the Committee and said she and her colleagues would be glad to return to the Committee any time it wished them to do so. Professor Hamilton thanked them for joining the meeting.

2. The Kept University

Professor Hamilton turned next to a draft statement on "Private Support of Research (Corporate Sponsorship)" that had been distributed to the Committee. (The draft follows.)

Private Support of Research (Corporate Sponsorship)

Introduction

The Senate Research Committee discussed the implications to the University of Minnesota of issues raised by the article "The Kept University" published in the year 2000 by the *Atlantic Monthly*. There were sufficient disturbing aspects in the article that it was felt that the Committee should develop a set of general principles that could guide the University of Minnesota if a situation arose such as that described in the article. (Describe the situation)

Recommendations

The Senate Research Committee believes that the following principles must be adhered to when accepting money from private sources:

- Faculty, departments and colleges should be encouraged to seek private support for their research endeavors, especially in areas in which federal, state or University sponsorship is not available;
- Acceptance of private support should be the prerogative of the University, not of the individual units or faculty;
- Care must be taken in negotiating contracts with private entities to assure that academic freedom is preserved, particularly with respect to the faculty's right to publish new discoveries in an appropriate timeframe, and with the faculty's right to choose the area of scholarship s/he wishes to pursue;
- Private sponsors should not have the right to unduly influence the content of publications unless there is proprietary information important to the sponsor;
- The University must exercise care that the receipt of private funds does not adversely affect distribution of University resources in areas that are not able to generate private support or alter priorities that might lead to the destruction of the core University.

Professor Hamilton said he had tried to distill the earlier discussion of "The Kept University" articles in a set of principles that could guide the institution. He did not deal with specifics, such as limiting the proportion of research any one company could support, intellectual property, and so on, and tried to reduce the draft to as few statements as possible.

Professor McConnell inquired what the University's policy on secrecy is. As he read this, he said, he was concerned about the public nature of research at the University and that he would be more comfortable when there is more disclosure. He said he was confused about when public disclosure would be possible.

Professor Hamilton said he took disclosure as a given. Mr. Wink said that is the University's stance toward all sponsors: the University/the faculty member must have the right to publish. Sponsors are given the right to review publications and to protect proprietary information, and publication will be delayed for 30-60 days (occasionally a little longer if intellectual property needs to be protected but rarely is the delay more than 90 days). There was a case recently; if language in a grant may preclude the right to publish, the issue is brought to this Committee to determine if the University's policy is being followed. But the University does not give away or delay long on publication rights.

Will this be a resolution or a policy and will it go to the Faculty Senate, Professor Hamilton was asked? He noted that the Faculty Consultative Committee has scheduled an "Intellectual Future of the University" session later in Spring Semester, the topic of which will be the issues raised by "The Kept University." This statement, if revised and approved by this Committee, could frame the FCC discussion. FCC could then decide whether anything should be forwarded to the Senate and in what form.

Committee members made a number of comments on the draft.

-- Private sponsors should have NO influence on the content of publications EXCEPT with respect to inclusion of proprietary information.

-- Support for University research can set directions for the entire institution and care must be taken in that regard. Professor Hamilton agreed and noted a thoughtful statement from a faculty member at Virginia Tech that could be incorporated: if the University accepts large amounts of money from outside sponsors, moves research in that direction, and then the money is withdrawn or no longer available, the University would be in a difficult position. This could be more of a problem in the humanities: not a donor shift, but a shift in the WAY funding is provided could change priorities.

-- There are also indirect cost implications: much of the University's research funding does not provide adequate support for the infrastructure. One concern is that the University would accept new funding that would carry no overhead, in which case the University would have to "rob Peter to pay Paul." That might be good for a department, or an individual PI, but "the University bleeds." Professor Hamilton agreed and said that federal research overhead is under-funded by mandate and the University tends not to receive overhead funding from private donors.

Mr. Wink said the University does not routinely waive overhead costs; for it to be waived in the case of a foundation grant, the foundation must have as explicit corporate policy that it does not fund overhead. Normally the University seeks full overhead funding.

That does not happen with donations from individuals, it was noted. And if funds are received without overhead, they can create a burden on a college.

-- As a public, land-grant institution, the University must be careful about exclusivity in research funding. It is important to define the University's relationship with those who provide funds.

Professor Hamilton agreed to mark up the draft and bring it back to the Committee at a future meeting for additional discussion.

3. Intellectual Property Policy Acknowledgement

Professor Hamilton recalled that the Committee found acceptable the legally-required Intellectual Property Policy acknowledgement that individuals will be required to sign; he asked that the Committee vote formally to approve it. He said he was not sure where this action should go next; it should, in any event, be distributed as widely as possible. That probably means it should be taken to the Senate.

Does this mean, Professor Poppele asked, that the Committee is voting to obey the law? It does, Professor Hamilton agreed.

The Committee voted unanimously to approve the language.

Professor Hamilton adjourned the meeting at 2:40.

-- Gary Engstrand

University of Minnesota

* * *

January 18, 2001

David W. Hamilton, Ph.D.
Chairman, Senate Research Committee
4-135A Jackson Hall
Minneapolis Campus

RE: Senate Research Committee Meeting Minutes December 18, 2000

Dear Professor Hamilton:

Members of the Institutional Review Board (IRB) and Institutional Animal Care and Use Committee (IACUC), involved institutional officials and staff of the Research Subjects' Protection Programs have reviewed the meeting minutes of the Senate Research Committee from December 18, 2000. We feel compelled to respond to Item 3 of the minutes on animal and human subjects research, because this section contains some misunderstandings about the federal legal requirements for subjects' protection.

At the outset, we acknowledge and agree that:

- There is a tension which appears at the interface between evaluation of scientific merit and evaluation of subjects' protection;
- The "principal" role of the IRB/IACUC is to evaluate subjects' protection; and
- It is problematic when the IRB/IACUC is the only agency providing oversight and merit review;

However, we respectfully point out that:

- The universe of scientific merit review and that of subjects' protection review are intersecting universes rather than separate, because study design considerations have direct implications for subjects' protection;
- Scientific merit review by funding agencies rarely includes specific assessment of the adequacy of subjects' protections or the possibility of minimizing risk or enhancing potential benefit through alterations in design;
- IRBs and IACUCs are required under federal regulations to consider scientific merit in relation to subjects protection; and
- A statement by the University Senate directing the IRB and IACUC on how to conduct aspects of their review processes is not compatible with the level of authority and autonomy granted these bodies under federal regulations.

We have enclosed a response to the Senate Research Committee minutes which discusses the legal and ethical framework for subjects protection. We respectfully request that this response be appended to Section 3 of the minutes to the extent these minutes are approved and become part of the official Senate record. We also ask that an introductory statement be added to Section 3 which calls attention to the appended response at the end of the section. Finally, for all the reasons outlined here, we respectfully request that the Senate Research Committee withdraw the proposed statement on human/animal subjects research from further consideration.

Sincerely,

/s/

Christine M. Maziar
Vice President for Research
Institutional Official for the Human Subjects Program

/s/

Richard W. Bianco
Assistant Vice President
Institutional Official for the Animal Care Program

* * *

RESPONSE TO SENATE RESEARCH COMMITTEE MINUTES OF 12/18

The proposed statement and ensuing discussion on research using animal and human subjects, which was presented at the Senate Research Committee meeting of December 18, 2000, reflects some misunderstandings about the federal legal requirements related to subjects' protection. It is true the primary purpose of review by an Institutional Review Board (IRB) and an Institutional Animal Care and Use Committee (IACUC) is to evaluate and assure the protection of human and animal subjects respectfully. However, this evaluation is not independent of the question of scientific merit. The federal regulations and underlying ethical principles governing the creation and operation of human subjects and animal care committees require these bodies to consider scientific merit in relation to subjects' protection.

Human-Subjects Research

Before an IRB can approve a research project, it must determine that several requirements are satisfied. Two of these requirements relate to scientific merit as follows:

- (a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:
 - (1) risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk . . .

- (2) risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects and the importance of the knowledge that may reasonably be expected to result. . . . 45 C.F.R. § 46.111(a) (emphasis added).

These requirements have their genesis in landmark ethical codes for human subjects protection – such as the Declaration of Helsinki, first adopted by the World Medical Association in 1964, and the Belmont Report, authored in 1979 by the National Commission for the Protection of Human Subjects of Bio-Medical and Behavioral Research.

The Helsinki Declaration addresses the relationship between scientific merit and subjects' protection in several basic principles: Biomedical research involving human subjects must conform to generally accepted scientific principles and be based on a thorough knowledge of the scientific literature; the researcher must be qualified and must bear responsibility for the human subject even though the subject has given consent; human subjects research cannot legitimately be conducted unless the importance of the objective is in proportion to the inherent risk to the subject; and concern for the interests of the subject must always prevail over the interests of science and society. World Medical Association Declaration of Helsinki, adopted 1964 and amended 1973, 1983 and 1989, published in *Protecting Human Research Subjects: Institutional Review Board Guidebook*, NIH 1993, Appendix A6-3 through 6-6.

Serving as the foundation for federal policy on human subjects protection, the Belmont Report offers basic ethical principles as well as specific guidance to human subjects review committees. The Report states:

...[T]hose making decisions about the justifiability of research [need] to be thorough in the accumulation and assessment of information about all aspects of the research and to consider alternatives systematically.... Thus, there should first be a determination of the validity of the presuppositions of the research; then the nature, probability and magnitude of risk should be distinguished with as much clarity as possible. *Protecting Human Research Subjects: Institutional Review Board Guidebook*, NIH 1993, Appendix A6-7 through 6-14.

In order to satisfy legal and ethical mandates, IRBs must consider scientific merit in relation to subjects protection. While other review bodies can and should be the primary reviewers of scientific merit, the IRB cannot defer its obligation in this regard--with or without the existence of a qualified peer review.

Activities Involving Animals

Scientific merit also is a relevant factor in the federally mandated review process for activities involving animals. Principle II of the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training states:

Procedures involving animals should be designed and performed with due consideration of their relevance to human or animal health, the advancement of knowledge, or the good of society. Public Health Service Policy on Humane Care and Use of Laboratory Animals, <http://grants.nih.gov/grants/olaw/references/phspol.htm>.

Although institutional animal care and use committees do not prescribe standards of research design or performance, 9 C.F.R. § 2.31(a), they do consider scientific merit in at least two ways. First, principal investigators must provide written assurance to the IACUC that their proposed activities do not unnecessarily duplicate previous experiments. 9 C.F.R. § 2.31(d)(iii). Further, proposals submitted to the IACUC must contain several elements, including: “A description of procedures designed to assure that discomfort and pain to animals will be limited to that which is unavoidable for the conduct of scientifically valuable research...” 9 C.F.R. § 2.31(e)(4) (emphasis added).

The federal regulations on animal welfare apply to all research, testing and teaching procedures using laboratory animals. 9 C.F.R. § 1.1. Further, they make no distinction between the use of animals that are reared and bred for research from those that are not. In all activities that involve animals, the investigator must provide “a rationale for involving animals, and for the appropriateness of the species and numbers of animals to be used.” 9 C.F.R. § 2.31(e)(3). Moreover, individuals who use animals in activities must receive training and instruction in several areas, including the “concept, availability, and use of research or testing methods that limit the use of animals or minimize animal distress,” 9 C.F.R. § 2.32(c)(2), and instruction in how to find information “on alternatives to the use of live animals in research.” 9 C.F.R. § 2.32(c)(5).

To meet their obligations, IACUCs must ensure that all proposed activities involving animals meet rigorous standards, including standards related to scientific merit. The use and/or killing of animals cannot be approved without reference to the validity of the science and the potential knowledge to be gained.

Funded versus Unfunded Research

There is no distinction between funded and unfunded research for purposes of subjects’ protection. The principles and standards outlined above apply regardless of funding status. The IACUC regulations established under the Animal Welfare Act apply to all animal activities at this University, irrespective of federal sponsorship, because we are a research facility that purchases or transports live animals. 9 C.F.R. § 1.1. Further, we have entered into an Animal Welfare Assurance Agreement with the federal Office for Laboratory Animal Welfare (OLAW) certifying our compliance with these regulations.

Regarding human-subjects research, the University has a Multiple Project Assurance with the federal Department of Health and Human Services for protection of human research subjects, as required by the federal regulations. Under this assurance filed with the Office for Human Research Protection (OHRP), the University certifies that it will comply with all requirements of the federal regulations (45 C.F.R. 46) and the ethical principles of the Belmont Report for all non-exempt human subjects research, regardless of source of support.

Academic Freedom and Responsibility

Academic freedom is an important and cherished principle of institutions of higher education. However, this freedom is not absolute. Moreover, the opportunity to conduct research involving human subjects (and by analogy animal subjects) is not recognized as a substantive legal right under federal law. In a legal order issued in 1996, the federal district court in Minnesota upheld the decision of the University’s IRB to suspend a faculty member’s research following an investigation into research violations. *Halikas v University of Minnesota, et al.*, 4-94-CV-448 (D.Minn. 1996). The Court found no

violation of the researcher's procedural rights and also concluded: "There is no substantive due process right to conduct human-subjects research." *Id.* at p. 7.

Academic freedom and subjects' protection can and do function compatibly for the most part. However, the academic freedom of faculty cannot override the legal protections afforded research subjects, including those protections that call for human subjects and animal care committees to consider scientific merit in their review processes.

Status and Role of IRB/IACUC

Both the IRB and the IACUC have a different status than other faculty committees at the University. These bodies are established by federal regulations and operate under explicit standards mandated by federal law. They have exclusive authority to review and approve, deny or require modification in proposed research/activities involving human and animal subjects. 45 C.F.R. 46.109(a); 9 C.F.R. 2.31(c)(6). Their considerable autonomy is expressly recognized in corollary federal regulations, which state that no one at an institution can approve human-subjects research or an activity involving animals if it has not been approved by the IRB/IACUC. 45 C.F.R. § 46.112; 9 C.F.R. § 2.31(8) (emphasis added). A statement by the University Senate directing the IRB and IACUC on how to conduct aspects of their review processes is not compatible with the level of authority and autonomy afforded these bodies under federal law, and could be viewed as an institutional failure to live up to our assurance agreements with the federal government.

Service Issues

An important distinction must be made between the workings of the IRB and IACUC committees, their decision mandates, and the *service* provided by the Research Subjects' Protection Programs' staff. Resource issues have affected the operation as new mandates and increased workloads have stretched the resources very thin. Additional resources were identified for this fiscal year and additional staff and system improvements are underway. It is hoped that these changes will improve turnaround time. However, specific examples of the delays would be helpful for analysis and problem solving.

All faculty are encouraged to serve on the IRB and IACUC committees. Faculty who have concerns about the workings of these groups could use this opportunity to provide their input into the committee's decisions, and also could use the knowledge they gain to facilitate preparation of their own IRB/IACUC applications