

**Northwestern University**  
**Minutes of the University Senate Meeting**  
**November 18, 2004**

The University Senate held its first meeting of the 2004-2005 year on November 18 in Hardin Hall on the Evanston Campus. President Bienen called the meeting to order at 3:30 PM.

I. The minutes of the June 1, 2004 meeting were approved unanimously without changes.

II. In accordance with two Resolutions of the Senate in past years, first term associate professors and all assistant professors may be elected to Senate membership by a Senate vote upon nomination as stipulated in the University Statutes. A resolution on the floor that all faculty of the rank of assistant and associate professor as nominated by their respective schools be elected to membership in the University Senate was seconded and passed by unanimous vote.

III. After non-members of the Senate were excused, Associate Provost John Margolis presented nominations for honorary degrees on behalf of David Besanko, Chair of the Committee on Honorary Degrees. Approval was sought for eight nominees. Approved nominations, which are held in confidence, will go to the Board of Trustees.

IV. Following re-admission of observers, Professor Lewis Smith presented an overview of the Institutional Review Board, whose mission is to oversee research involving human subjects or materials obtained from human subjects. Only four years ago, there were only two IRB panels, both meeting on the Chicago campus with a total of two meetings a month. The Associate Vice President for Research oversaw animal care and use committee chair and the IRB chairs; there was a director of the office for the protection of research subjects and one (later one and a half) coordinator. There was one support staff member beyond that. Currently, there are a total of five panels, four of them biomedical panels meeting in Chicago and one meeting exclusively on the Evanston campus. Each panel meets once a month, making a total of five meetings monthly. After listening to suggestions from the investigator community a separate social and behavioral panel and focused biomedical panels were formed. The IRB is also beginning to confer with regional and national IRBs with the intent being to diminish the load on our own IRB by avoiding duplication of effort when the same project is under review at multiple institutions. Smith presented a proposed organizational chart showing seventeen people supporting the IRB panels and five supporting the animal care and use committee. The office has grown considerably. The IRB is obligated by its agreement with the federal government to review research by anyone where human subjects or materials from human subjects are employed. Exempt research is determined by petition by an investigator to the IRB. This is usually done administratively. Northwestern has signed a Federal-wide assurance, as have other institutions like ourselves. The IRB must approve or disapprove a research project; none may be started without IRB approval. If the IRB

disapproves a proposed research project, the Administration cannot override the decision. However, a project approved by the IRB may be disallowed by the Administration. Federal guidelines outline the responsibilities of an investigator: qualification for the proposed research; an approved protocol and consent form; recruitment materials; and adherence to the conditions of research that have been approved. Deviations from any parts of an approved protocol must be reported. Changes to a protocol must be approved in advance: in a recent, widely reported incident, when a volunteer research subject died after an investigator at Johns Hopkins changed a protocol without prior approval, drastic sanctions resulted. Items reviewed by an IRB committee include periodic reviews, adverse events, revisions, and protocol violations. The Northwestern IRB now has a database showing the volume of work handled by the biomedical and social and behavioral panels. Through the end of September there were almost 10,000 submissions. The animal care and use committee had about 2,500 in the past year. Social and behavioral sciences account for about 8% of all submissions; the biomedical panel gets about 6,000 pages annually reporting adverse events. We have about 3,500 active protocols, including those for exempt projects and for Northwestern's hospitals in Chicago; the latter account for about 70% of those protocols. Research at some schools may not be proceeding under active protocols, and this problem is a concern to the Board. The total volume of research under IRB supervision shows some seasonal variation which is difficult to explain. Turnaround time between a project's entry into the IRB office and panel action or administrative resolution is at this report still being analyzed.

Responding to a question from Bruce Wessels about student research, Smith reported that undergraduate research has been handicapped by delays for approval. Advanced training in a research-intensive class should be provided to minimize time required for approval. In graduate research on both campuses, timeliness is likewise a key requirement. To a question from President Bienen about what other universities are doing in this respect, Smith replied that there is a Listserv for discussion of processes in place, especially for the student projects where results are likely to go beyond the classroom. How can it be known when this is likely to occur? In a minority of courses, publication of results is expected. Most courses concentrate upon methods, in which case publication is not planned. Retroactive remedies are mandated when it appears likely that publication will come from the latter category. What would happen in projects where Federal funding was involved in student research and such retroactive actions were not feasible? In such cases, the student would have to be added as key personnel, take the required training, and meet other requirements; in such projects, it is hoped there will be sufficient lead time. Martin Mueller asked what categories of research are clearly excluded from IRB review: do the protocols include correspondence or manuscripts of poets recently deceased who may have living relatives? Smith said, research on dead people is outside the purview of the IRB. But the application of rules to living relatives is a great issue in fields such as anthropology. This matter is currently being explored with a view to identifying areas of research outside of IRB review and approval. Eva Redei asked if the number of proposed laws will increase as a result of research in English, history, and anthropology. What criteria will reviewers be expected to meet? Smith said there are already plans for such an event. Dennis West is an IRB chair who no longer serves on a panel; he will examine proposals that are either exempt, have applied for exemption, or are expedited and can be reviewed outside an IRB panel meeting. On the Evanston

campus, plans are underway to establish an office with a coordinator, a department assistant, and senior staff who will come in on a rotating basis. Redei then asked if periodic reviews are going to the same panel each time or to a new panel unfamiliar with the project. Smith replied that there are advantages in having different panels review any project as this would reduce the likelihood of something being overlooked. Even if a project returns to the same panel, its members will change: even the primary and secondary reviewers on a panel may no longer be serving or available, resulting in the likelihood that old questions will be considered anew. Considerations of timeliness may also dictate that a project be assigned to a different panel than before. Questions of communication and availability also result in difficulties for researchers and IRB panels alike. In reply to another question, Smith explained that research developed in one class may be shared with another working on the same project in the same university confines without violating IRB protocols. Asked what procedures exist to assure consistency in the application of rules, Smith remarked that study sections in panels try to reconcile inconsistency; but in any process of judgement there are bound to be differences, as when one journal rejects a submission that another accepts with enthusiasm. Once rejected, however, a proposal cannot under present rules be simply passed along to another IRB panel. The presence of lay persons on IRB panels, he added, is expected to provide a perspective that may not occur to university faculty members. A panel's judgement may be appealed, and a project may be resubmitted: no rejection, therefore, is necessarily final. Though not perfect, the IRB system is working. Another questioner asked what distorting effects IRB regulations may have on science. One indicator is the subject pools, which begin at age 18 and exclude children. Smith agreed that the exclusion of children is a continuing problem and affects research in pediatrics as well as social and behavioral research. Eva Redei asked about projects in which the answer to a question is unanticipated and every step of the research requires approval of a new protocol, which can delay work for 30 days or more. Smith replied that the social and behavioral sciences panel has recognized this problem where additional research questions come to light in the course of a project, particularly overseas: an overall plan, not a rigid set of questions, is expected. Does the same expectation apply to biomedical research under certain conditions? It should, Smith replied, but it has not. The ultimate canon in such gray areas is protection of the research subject. Martin Muller returned to the relevance of IRB jurisdiction to the humanities. A recent biography of Graham Greene has various family members protesting that they have been slandered or defamed; does this fall within the domain of IRB? Clearly, in Smith's view, it should fall outside if the persons interviewed were willing to talk. The impact on others of what comes to light in this way is a gray area, he admitted, but such consequences are not easy to anticipate. This is terra incognita, outside the usual purview of IRB panels. Dean Loren Ghiglione of Medill asked what precautions investigators in Journalism should bear in mind with regard to IRB. Smith cautioned only that IRB oversight should not impede one's scholarly activity. Journalism has stayed out of the scope of IRB concern. Professional organizations in history and anthropology have argued strongly that their disciplines should not be placed under the same kind of scrutiny as the sciences. Journalists need to make themselves heard in the same way.

V. Vice President for Research Bradley Moore remarked that the Office of Research has been making every effort to develop a strong positive leadership in the various units and to foster a culture of service in the support of research.

VI. President Bienen spoke about the internationalization of the University with particular reference to access of foreign students, faculty, and postdoctoral students to Northwestern. Presidents of research universities like Northwestern met with Secretary of Homeland Security Tom Ridge in New Haven two weeks ago at the meetings of AAU research university presidents. Earlier, when President Bush was in New Haven for the graduation of one of his daughters, President Levin of Yale had taken this issue up with him and apprised him of the serious consequences for universities of having a slowdown in the processing of some visas and the rejection of others. Bush had replied that he was sensitive to this matter. Secretary Ridge reported to the university presidents assembled in New Haven that a significant amount of money had been put into new consular officials. Requests for visas at consulates go to numerous agencies such as Homeland Security and are bottled up in the bureaucracy. Secretary Ridge had data on the speeding up of the process at the consular level and subsequently. But there is still a marked decline in foreign graduate student applications and acceptances in the United States — not so much at Northwestern, as the stronger universities have been better cushioned against the impact of the slowdown. It is still a serious issue nationally, and the authorities in Washington understand the implications. We are trying to couch the matter for Secretary Ridge in security terms: national security does not depend only on monitoring who comes in, but also on the flow of skilled people who attend our universities, and stay to teach or go into the labor force for some extended period of time. The American citizenry does not produce enough people to fill the gap. Bienen was asked at this meeting what Northwestern is doing; but it is not an issue on which single institutions make much headway. He has talked with individual senators, congresspersons, and staff in Speaker Hastert's office where we have good access. As the channel of communication for research universities, the AAU has taken up the issue in Washington. This had made some difference; it remains to be seen how effective these interventions have been in re-opening foreign access to the American university system. Another issue, related to the first, is access to laboratories and materials by non-citizens. The strong view here is that anybody whom the U.S. government lets into the country to attend Northwestern in any capacity belongs to the same class of academic citizens: we don't do classified work on campus, we have no intention of doing so, and thus we see no reason to discriminate among categories of people, nor shall we do so. In response to a question from Bruce Wessels regarding the slow response time at Northwestern for processing visas and the difficulty of reaching staff at Northwestern by phone, Elizabeth Matthews, Associate Director of the International Office, stated that her office had been understaffed due to an extended medical leave, but a new hire has just been made and she anticipates being able to process applications within three weeks. This processing time may be longer, however, if the application is incomplete. When less than a month is requested for turnaround time, the chance of delay is increased: the scholar must set up a visa appointment at the consulate which can take 2 to 3 weeks, obtain documentation from the International Office at Northwestern (three weeks), and pay a fee of \$100 before entry to the U.S. is possible. Departments are therefore asked to allow 2 to 3 months for

the entry of an appointed scholar. President Bienen commented that because a medical leave severely impacts a very small staff, University procedures must be adapted to maintain necessary staffing levels. Steve Fisher said in this case the individual's medical leave kept being extended and the technical nature of the job precluded filling the gap with a temporary assistant. Wessels noted that the University of Michigan maintains a much larger staff in its international office proportionate to the size of the university, and that training and education of staff could make our office less vulnerable to staff shortages.

VII. Eva Redei, Chair of the General Faculty Committee, presented the report of the Committee, which is the steering committee of the University Senate, with nineteen representatives from all schools of the University. She explained that there are five standing subcommittees, each with its own agenda for the year. Suggestions for GFC action are welcome at any time and should be forwarded to her at any time, preferably by e-mail. The Budget Subcommittee seeks to understand the University budget process and its priorities, and promotes greater transparency in the budget process. The Benefits Subcommittee meets with the Associate Vice President for Human Resources; its current interests relate to the health care plan, mental health benefits, and parking fees. The Faculty Development Subcommittee looks into the effects of regulatory processes on research and education. It is also concerned with the definition of who is a faculty member, which faculty ranks are represented by what associations or organizations. The Education Subcommittee is currently looking into the effect of varsity athletics on educational priorities, the international nature of the University, and the effect of interdisciplinary operations on tenure. The Research Subcommittee is looking into the research enterprise. A common question of the GFC as a whole is why is the faculty role in governance so much less now than before, and how can that be changed? Faculty Senate meetings were not so long ago attended by 130 to 150 members. The GFC is looking for ways to restore the conditions that elicited such a high level of participation.

VIII. John Margolis reported that all nominees for honorary degrees had been approved by the ballots distributed earlier at this meeting. There being no remarks by President Bienen and no new business to come before the Senate, the meeting was adjourned at 4:37 PM.

Respectfully submitted,

Daniel H. Garrison  
Secretary to the University Senate