

university of minnesota memo

To David Lenander, Chr., Bus. & Rules Comm

From Marilee Ward

- For your information
- For your approval
- Per your request
- For your attention
- Note and file
- Note and return
- Note and forward
- Please advise
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Attached are proposed amendments to the Rules of the Senate affecting the Human Subjects in Research Committee.

The Committee on Committees will take them up tomorrow & if it approves them, they will be forwarded to Business & Rules, for forwarding to the Senate for the Apr. 16 meeting.

The face sheets provides a summary of the changes.

Date 3/3/87



Professor Williams:

The Board of Regents' Policy on Principles and Procedures Related to the Use of Human Subjects in Research was last approved on February 11, 1983.

A section of that policy statement includes the description, membership, etc. of the Use of Human Subjects in Research Committee.

Since February 1983, the Health and Human Services Office for Protection from Research Risks has revised federal regulations governing this area. The Human Subjects Committee, therefore, has completed a new draft of the Policy statement to reflect the changes in federal regulations and will be submitting it to the Board of Regents for approval after the Senate approves the attached proposed revisions to the committee's description, membership, etc.

The proposed changes before our committee have been approved by both the Use of Human Subjects in Research Committee and the Research Committee. If we approve them, the motion will be forwarded to the Consultative and Business & Rules Committees for inclusion on the April 16 Senate agenda.

The main changes are in the description of how the Human Subjects Committee functions and in the membership. They include:

1. Changing the description of the committee to function as "three committees" instead of as one committee divided into subcommittees and review panels. The new guidelines specify the membership for each committee instead of for the committee as a whole.
2. Selection of the at-large community members has been greatly simplified.
3. Elimination of the wordy job description of the administrative assistant. This is a Graduate School appointment and to have a detailed job description in our Senate Rules isn't consistent with other Senate or Assembly committee charges.

The duties and responsibilities are only slightly changed.

COMMITTEE ON COMMITTEES

USE OF HUMAN SUBJECTS IN RESEARCH COMMITTEE

Action (10 minutes)

MOTION:

To amend the present University Senate Rules, Article IV, Section 7, to change the description, membership, and duties and responsibilities of the Use of Human Subjects in Research Committee as set forth below: (additions are underlined and deletions have lines through them.)

7. Use of Human Subjects in Research

These shall be

to one of which shall
~~This~~ Three committees, reviews ~~proposed~~ *using* research and *covering the* use of human *subject*

all
supervises ~~approved~~ projects, to assure the fullest protection of the rights and welfare of the subjects.

Two of the committees review research projects in health and biological sciences; one reviews social and behavioral sciences research projects.

Membership

~~The~~ Each of the three committees shall be composed of at least ~~60~~ 12 members from the University community (faculty/academic professional, staff, and student body) and one ~~to 4~~ members from the community at large.

A. The members from the University community shall be drawn from the following categories:

- (1) ~~At least 20 members from the~~ Health ~~sciences~~ and biological sciences ~~(15 faculty and staff and 5 students)~~

(2) ~~At least 20 members from the Social and behavioral sciences (15 faculty and staff and 5 students).~~

(3) 2 members from the University Hospitals & Clinic administration.

(4) ~~At least 18 members from Other units of the University not included in (1), (2), or (3) (13 faculty and 5 students).~~

~~If the size of the committee is expanded to more than 60 members, the proportions of members from each of the above categories shall remain the same.~~

Each committee shall have no fewer than 12 members, at least 9 of whom shall be faculty/academic professional or staff and at least 2 of whom shall be students. Each committee shall include members from categories (1), (2), and (4) as the needs of the committees dictate. No committee shall consist entirely of men or of women or of members of one profession. Each committee shall include at least one member whose primary concerns are in non-scientific areas. *areas not using live human subjects in research.*

B. The members from the community at large shall be representative of the community and shall have demonstrated experience and/or interest in ethical issues.

Selection of members; Chair

A. University Community: The members of the committees

from the health and biological sciences and from the social and behavioral sciences shall be drawn from units in which a primary focus of professional activity is the conduct of research with human subjects in these areas, as well as from units having persons qualified to help clarify ethical, moral, and legal issues and ~~units having persons~~ ^{-matters-of-} ~~qualified~~ to discuss the relevance of research to the common good. ~~Such Members shall be chosen~~ appointed by the president, ~~or by a vice-president designated~~ ~~by the president~~ ^{upon} submission of nominees ^{through} ~~by the administrative assistant to the Senate~~ Committee on Committees. ~~Members shall be assigned to specific committees by the administrative assistant.~~

Deleted

The chairs of the committees - ~~health-and-biological-~~ ~~sciences-review-panel-and-the-chair-of-the-social-and-~~ ~~behavioral-sciences-review-panel-serve-as-co-chairs-~~ ~~of-the-full-committee.~~ - They shall be elected by a majority of the appointed members of each committee ~~the relevant review panels~~ by ~~a~~ mail ballot, ~~majority vote, for a period of two years.~~

~~Chairs of the health sciences committees must have a medical degree.~~

Deleted

- B. Community at Large: The members from the community at large shall be ~~selected by an ad-hoc subcommittee~~ ~~composed of members of the Use of Human Subjects in~~

~~Research Committee. - The members of the ad hoc committee shall be appointed by the chair of the parent committee. - appointed by the president upon submission of nominees by the administrative assistant and the committee chairs. Each community member shall serve one year and shall be eligible for reappointment.~~

~~The ad hoc committee may elect to identify 2-- additional community members to serve as alternates. One alternate would be assigned to the health-sciences subcommittee and one to the social-sciences subcommittee. - These alternates shall attend meetings only when the appointed community member must be absent. - Each community member shall be assigned to one of the four committee panels by the ad hoc committee.~~

~~(1) - Terms: - Each community member shall serve one-year (12 months) and shall be eligible for reappointment.~~

~~(2) - Criteria: - The criteria for committee membership shall be established by the ad hoc committee.~~

~~(3) - Confirmation of Appointment: - Appointments of community members shall be confirmed by a simple majority vote of the Use of Human Subjects in Research Committee and by approval of the University administration.~~

~~Panels and Subcommittees~~

~~The committee shall operate by means of subcommittees composed of two review panels each, representing the health and~~

~~biological sciences and the social and behavioral sciences. Members of the panels, as well as panel chairs, shall be appointed from the full committee by the executive secretary with the approval of the chair of the appropriate subcommittee. Each panel shall have no less than 9 members, 6 of whom shall be members of the faculty. The function of the panels shall be to review and approve individual proposals within the panel's domain, acting within one month of submission. Action may be taken by each panel when at least 5 members are present, at least 3 of whom are faculty members. Panel recommendations shall be by majority vote with the opportunity for an expression of a formal minority opinion.~~

Subcommittee on Policy

The committees shall also have one ~~executive~~ subcommittee on policy, which shall formulate committee policies. Members of the ~~executive~~ policy subcommittee shall be the chair of each ~~review panel committee, the co-chairs of the full committee if different from the chairs of each review panel,~~ one student representative, ~~and~~ one community representative ~~or~~ and other invited members of the committees who may have special interest in the proposed agendum. The subcommittee chair shall be elected by a majority of the subcommittee members. ~~Any committee member may petition the subcommittee for review of any policy statement formulated and approved by the subcommittee and may request that the issue be brought to the attention of the full committee for its action.~~ New

policies or changes in policy approved by the subcommittee shall be made known to all members of the committees by way of minutes of the subcommittee meeting and shall be voted on and approved by a majority of each committee at subsequent meetings of the committees. ~~[A majority of the full~~ each of the committees shall be required to veto any subcommittee action.]

Delete

~~Executive Secretary~~

Administrative Assistant

Staff support for the committees shall be provided by the Graduate School. The ~~executive secretary~~ shall be appointed ~~by the president for a three-year term, subject to reappointment for successive terms,~~ administrative assistant has an annual appointment in the Graduate School, subject to renewal for successive terms. He/she ~~and~~ shall not be a voting member of the committees or ~~of its subcommittee~~ or panels, but shall be entitled to attend committee, subcommittee, or panel meetings. The ~~executive secretary~~ administrative assistant shall handle the administrative work of the committee, ~~;~~ schedule meetings; and maintain records for the committee, subcommittee, and panel meetings, including formal requests for approval of research projects, minutes of all committee, subcommittee, and panel meetings, and the formal decisions of the committee and its subcommittees and panels, together with copies of all letters of approval sent to the investigators and any periodical reports by investigators to the committee, as may be required by the procedures of the

-committee-

Duties and Responsibilities

- to provide ~~prior collegial~~ review of proposed research involving human subjects - prior to its initiation.
- to provide continuing supervision and advice with respect to approved projects of research involving human subjects.
- to initiate specific statements of policy and procedures necessary to carry out the institutional responsibility of the University with regard to the use of human subjects in research, subject to review and modification by the University Senate. These statements shall be binding on ^{on policy} ~~the committees and subcommittee~~ ~~s~~ ~~and panels~~, members of the faculty, academic professionals, and staff of the University, and other individuals engaged in research involving the use of human subjects carried on under the auspices of the University.
- to submit an annual report to the Senate through the Senate Consultative Committee.

COMMENT:

To comply with federal regulations issued by the Health and Human Services Office for Protection from Research Risks, changes are proposed in the description, membership, and duties and responsibilities of the Senate (Operations) Committee on the Use of Human Subjects in Research.

C. ARTHUR WILLIAMS

Chair

university of minnesota memo

To Penny Krosch

From Martha Kvanbeck, Senate

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The attached items were distributed at the University Senate meeting yesterday (April 16, 1987).

Date _____

University Senate meeting, April 16, 1987

INFORMATION

The following excerpt from the minutes of the November 6, 1986, meeting of the University Senate is provided for information.

XXI. NEW BUSINESS

CENTRAL INTELLIGENCE AGENCY (CIA) ON CAMPUS

RESOLUTION:

This resolution is to be introduced November 6, 1986, at the fall quarter 1986 University Senate meeting, for consideration by the Committee of Social Concerns and SCC during fall and winter quarters.

WHEREAS the CIA has violated international law and has committed acts of violence against people and property in many nations;

WHEREAS the University policy concerning recruitment needs to be studied at a Senate committee level;

THEREFORE, BE IT RESOLVED that the Senate Committee of Social Concerns be urged to investigate University recruitment policies and to discuss the intent of the CIA's presence in a University setting;

AND, BE IT FURTHER RESOLVED that it is the sense of the University Senate to discontinue providing University offices and services for the CIA in their interviewing of students on the University of Minnesota campuses.

BRENDA ELLINGBOE
CLA Senator

As an item of new business the resolution was referred to the Senate Consultative Committee for consideration at a future meeting of the Senate.

FACULTY DEVELOPMENT COMMITTEE
SECOND PROGRESS REPORT TO THE FACULTY SENATE

April 16, 1987

Charge to the Committee: Develop a set of recommendations for implementation of proposals, related to faculty development, that have come from the work of recent faculty committees (Senate Committee on Faculty Affairs, the Merwin Committee, etc.).

Current State of Committee's Work: Subcommittees have presented some sections of the report in initial draft form to the entire committee for review and comment. Some revisions have been made and a draft for the committee report is being written. Other sections of the report (e.g. salaries) are still being worked on by subcommittees.

Committee's Schedule: The committee plans to have the entire report in draft form by the May 14th Senate meeting. This will allow the last two weeks of May for review and revisions prior to the June 1st submission date. The report will be submitted to the Faculty Consultative Committee and the President.

TENTATIVE OUTLINE FOR REPORT

Section I: New plan for faculty salaries, based on new goals. A subcommittee is continuing to make salary comparisons and to look at salary trends over the past few years. They are considering proposing a comparison group that includes only part of the Big 10 institutions plus comparable public and private institutions in other parts of the country.

Section II: Sabbatical and Single Quarter Leaves. A draft report has been presented and discussed by the entire committee. The proposal builds on the idea of flexibility, presented in the report of the Senate Committee on Faculty Affairs, and probably will recommend some financial support to improve use of leaves. It recommends giving responsibility for leaves to colleges, operating within guidelines established for the entire Twin Cities Campus.

Section III: Support for the work of the faculty. A draft report, examining several items of this nature has been presented to the entire committee. In part, it suggests a mechanism to focus attention on faculty/staff ratios during planning and staffing decisions, identifies some specific civil service policies related to vacations and leaves that need examination, recommends automation of the grants management operation (coordinated with automation of the purchasing and accounting system and plans for computer networking), and recommends the preparation of a policies and procedures handbook for department heads/chairs. Other recommendations relate to facilities and space management. One subcommittee continues to work on recommendations related to the Library and another on faculty appointments (9 vs. 12 mos.) and work-loads.

Section IV: Workshop for department chairs/heads. Several items have been identified as ones with which department chairs need experience in order to best support the work of the faculty. For example, certain aspects of management of resources; working with the faculty in career development, counseling on personal problems, working with civil service policies, etc. involve skills learned through experience. We will likely propose that experience gained by outstanding heads/chairs be made available to those less experienced in something like a workshop form.

Section V: Areas in which we can make no implementation recommendations. Several items are being collected into this section, including faculty fringe benefits (because the new tax law has introduced many new uncertainties that are not yet sorted out), faculty use of computers (there is a special committee working in this area), etc. We intend to suggest who should follow-up on these items.

Meeting of the University Senate
Thursday, April 16, 1987

Questions to the President

The university administration proposes to "dis-establish" the Dept. of South and Southwest Asian Studies. Numerous letters voicing strong support for the Dept. and its faculty from leading scholars in the South Asian and Middle Eastern academic areas have recently been sent to Vice President Benjamin and yet they are apparently being ignored by central and CLA administration. The University of Minnesota can never hope to be ranked in the top five nationally without departmental coverage of India, Pakistan and the Middle Eastern countries which is the Dept. of South and Southwest Asian Studies *raison d'être*. Does central administration seriously propose to go ahead with CLA's plan to eliminate this department?

Professor Indira Junghare
Department of South and
Southwest Asian Studies

Is it anticipated that faculty now with tenure or on tenure track may fail to be retained as a consequence of the reorganization or abolition of departments or programs?

Regents' Professor Leonid Hurwicz
CLA Senator