

Senate Research Committee*
Wednesday, December 1, 1993
238 Morrill Hall

PRESENT: Albert Yonas (chair), John Basgen, Signe Betsinger, N. L. Gault, Jeylan Mortimer, Anne Petersen, Stephen Rich, WinAnn Schumi, Kirk Walstoni

REGRETS: Sara Evans, Daniel Feeney, Eric Klinger, Khoi Nguyen

ABSENT: Kirk Allison, Liz Eull, Allen Goldman, Tony Potami

OTHERS: Mark Brenner, Fay Thompson

1. Minutes

The minutes for the previous meeting were approved.

2. DRAFT STATEMENT ON RESEARCH CLIMATE

Professor Yonas proposed to send a copy of the draft to Anne Petersen, Vice President for Research, regarding this issue so that a dialogue could begin between her and the committee. The committee was particularly concerned about the lack of emphasis on research at the coordinate campuses, particularly Morris. A committee member indicated that Dr. Petersen would cover a number of related matters about strategic planning later in the meeting.

3. IRB REVIEW COMMITTEE RECOMMENDATIONS

The chair introduced Dr. Mark Brenner to describe the status of the Institutional Review Boards (IRB) at the University which reviews research projects involving human subjects. The FDA came and performed a site visit producing 23 concerns, many of which were very serious. As a result, the University has been developing a response. This past summer, the University was formally charged to report to the FDA and the Office of Protection for Research Residents (OPRR - under Health and Human Services). Areas which needed greater level of investigation surfaced by evaluating several past cases (Garfinkel and MALG), the surgery department, and the data system - specifically the renewal process which reviewed cases on a mass level rather than individual ones. The University was required to provide an explanation and produce a plan of response to these concerns. The response to the FDA has been submitted in the form of a 500 page document. Mr. Brenner expects the FDA to see that the University is acting responsibly, and therefore not revoke its privilege to conduct research with human subjects.

The actions the University is to make that are stated within the document include the creation of a faculty leader position in the IRB to work with the advisory committee. The advisory committee feels that it is very important that there is faculty ownership and clear connection to higher administration on the activities of the IRB. The intent of these initiatives is to raise the credibility and the visibility of the IRB. Funds are now available for a new position titled Assistant Vice President for Research - Compliance

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Officer. The person holding this position will provide leadership for the IRB among other things. The University has also learned that measures for insuring the safety of human subjects is only to be reviewed by the IRB. The IRB office has been given a larger budget, and is currently adding new positions to meet the demands of the FDA. The new staff members will serve the increasing number of committees (which are called IRBs) reviewing the growing number of research projects in medicine and social sciences. Cases will be categorized according to their level of risk so that review will be more stringent for those cases which pose a greater chance for problems. A more sophisticated computer system will enable the IRB office to deal with annual renewals more effectively, and provide on-line information relating to the approval process. Emergency request approvals can no longer be used repetitively as has been conducted mostly with cases related to medication.

There is a need for educational programs for faculty, staff and students to understand the requirements and responsibilities of working with human subjects. A program is now being organized for this purpose, and on a broader scale to address responsible conduct in science as a whole. The advisory committee is concerned that the IRBs may be reviewing student research cases which have not been evaluated by their faculty mentor. This committee would prefer that faculty be the conduit between the students and the IRBs.

Questions from the Committee:

A committee member stated that coordination of approvals between the University and other hospitals or institutions may be difficult because they often have IRB processes which are more stringent than here. What will the coordinator be doing to facilitate this? Dr. Brenner stated that this person will make sure there is an ongoing dialogue to determine the roles of all people and institutions involved. This committee member also mentioned that senior faculty should be encouraged to participate in the IRBs because junior faculty may not have the breath of experience in human investigation. Mr. Brenner said that suggestions were given that when those involved in human investigation sign the agreement, they should also be signing that they are willing to be involved in an IRB.

Another committee member said that the second to last statement on the Facts Sheet needs to be more specific in regards to stating exactly what needs to be controlled within a research project involving human subjects (even when a researcher collects pilot data). Through various questions, Dr. Brenner said that relying on the IRB Office should become more frequent as ambiguity arises. A committee member said that he did not know if expecting the IRB Office to "police" all cases was realistic. Dr. Brenner expressed that the new evaluation system using faculty should take care of most of the monitoring, but said he would share this committee person's suggestion with committee leading this review of the IRBs. Committee members also discussed notifying IRB chairs of high risk cases, human subjects' satisfaction, as well as cost and ethics of patient follow-up.

PROPOSED REVISIONS OF THE CONFLICT OF INTEREST POLICY

Dr. Brenner was also in charge of presenting several substantive changes that have been recommended for the draft policy dated November 23, 1993. On page 6, lines 153 and 154, CATEGORY IV: "An ACADEMIC EMPLOYEE may not personally receive royalties for texts of other materials he/she assigns for courses," is proposed to be deleted. Dr. Brenner said that although this rule was admirable, it would be a managerially impossible to implement. In place of this rule, a footnote will be added to the "ACADEMIC EMPLOYEE" statement in CATEGORY I on line 71 referring faculty to acquire

departmental approval for using their own writings in courses they teach. Therefore, faculty will be able to earn royalties in this type of situation.

On page 6, lines 163 - 166, CATEGORY IV, dealing with self referral, is currently being considered to state that one cannot be involved in self referrals in their professional area instead of including all areas.

The next proposed change is in the area of "Financial Interest" on pages 9 - 10, lines 290 - 294. The statement currently read that an "ACADEMIC EMPLOYEE" must disclose business interests which exceed \$5,000 in equity or annual income. This is proposed to be changed to state that an academic employee would need to disclose any business interests in the following areas:

- receive in excess of \$5,000 in annual income
- holds equity of \$25,000 or more in stock
- holds 1% or more of a company

Dr. Brenner then went on to speak about the approval process. Using some diagrams, Dr. Brenner described that there are two types of approvals. Category II cases have a small potential for conflict of interest. The department head has jurisdiction over this matter unless the he/she requests for review by a Conflict Review Committee. Department heads would submit an annual report to their Deans detailing all Category II activities. Category III include cases in which conflict of interest is possible. The department head would primarily review and make any recommendations, and then forward it to a Conflict of Interest Committee. This information would then be channeled back to the Dean (who would consult with the department head) to make a decision. If the Dean thought that further consultation was necessary, he/she would forward the case to a Public/Private Partnership Committee comprised of business and public representatives, and 25% U of M faculty. They would send its recommendation back to the Dean for the final decision. The Dean would present an annual report to the appropriate Vice President detailing all Category III activities. Also, a summary should be sent to the Public/Private Partnership Committee members.

Several administrators have recommended striking lines 120 - 121 from CATEGORY III which describes the need for disclosure when academic employees participate in product evaluation or clinical trials in which they hold some financial interest. This statement currently reads such that disclosure would not be necessary if "receipt of royalties (were) under the University's of another academic institution's royalty-sharing policies." Dr. Brenner asked for the Committee to give their opinion on this suggestion. The Committee and Dr. Brenner discussed this issue and decided it was a positive recommendation.

The final document is expected to go before the Senate in February.

PREVIEW OF STRATEGIC PLANNING

Anne Petersen presented the Committee with a summary of the report on research compiled by the Research Strategic Planning Committee (RSPC). The report consisted of reviewing the external environment; including the nation, state, industry; and the internal environment; the University.

In reference to the external environment the following specific issues were addressed:

1. National

- decreasing public trust of quality undergraduate education
- neglect by universities of important social or economic issues
- misappropriation of funds at educational institutions
- decrease in funds available for research from national level to universities
- institutions other than universities are being used to fulfill research needs
- pressure on indirect costs - perception as fun money, fraud, pilot research, who is this fun money for,
Congress sees this as money that universities don't need
- increasing need to have collaborative research

2. State

- In comparison to other states, Minnesota is doing pretty well financially. Nevertheless, financing for education is emphasized at the K-12 level by the state legislature. Post-secondary education funding is perceived as discretionary.

3. Industry

- many closing their R&D shops. Universities may be able to perform these responsibilities instead.
- cultural differences between industry and universities. Their funding for research at universities must be considered before determining their demands as infringing.
- increase in number of potential conflicts of interest
- these issues could greatly influence the nature of universities, especially when considering academic freedom

In reference to the internal environment to following information was detailed:

- the U of M is still a top university with a rich reputation and history, but there is concern of slipping (Are we trying to do too much?)
- quality is a big issue. With tighter funds, the University needs to have quality and be efficient.
- the University cannot maintain status quo. Major changes are expected to occur within higher education in the next ten years, and the University will slip quickly if it does not take part in change.

A set of recommendations were developed by three subcommittees within the RSPC including:

1. Accessing quality and strength in an ongoing way needs to be developed to a greater degree. Better collection of data will indicate which departments are doing a good job on research;
2. Examine the program review process - link strategic planning and traditional review process through the graduate school;
3. Interesting research in graduate enterprises need to be linked with resources - collaborative work might help in acquiring the funding;
4. Personnel policies must aim for high quality and a diverse faculty;
5. The Graduate School must be more involved in hiring, tenuring, and retention issues;
6. Graduate school data on student input, progress, and outcomes of where students go after graduation needs to be improved;
7. Applied master degrees should be increased - This idea has met with resistance; and
8. Does the University have too many programs -- too many that are too small?

The U2000 document says little about research. The RSPC hopes that this report will bring substantive data and issues to begin a dialogue as strategic planning progresses.

- Kevin Gormley

University of Minnesota