

MINUTES*

Senate Research Committee Subcommittee on Disclosure Policy January 30, 1991

Present: Mark Brenner, Sam Krislov, Tony Potami, John Sullivan, John Thuente, Albert Yonas

Dean Brenner began by observing that the University leads many universities in the matter of disclosure policy. The present document was developed earlier than most and remains a good one, but it can be enhanced. Addressing issues that have surfaced on the national scene will enable Minnesota to keep its lead. Suggestions for changes were in the following areas.

1. Public Statements

Page 5, item G, requires personnel with an interest in a company to refrain from making public statements in regard to sponsored research prior to publication of results. This needs clarification in regard to what now defines "publication." When the document was written it was meant to preclude statements made to, (for example) shareholders, until the scientific community had been informed of results. The question also remains of whether once the research is published the person should continue to disclose the relationship, e.g., at board meetings or when giving expert testimony. This is similar to giving due credit for grant support.

Tony Potami said he considers this a good idea. An investigator shouldn't be embarrassed to say, "I did this research, and by the way, I'm a consultant for X company." Such statements are hard to monitor, but a code of ethics seeks to avoid problems by a statement up front. Sam Krislov suggested that it should be stated as an expectation, not a mandate. Too rigid a requirement might be thrown out as a violation of First Amendment rights, and it would not be desirable to put people on the spot if they make just a two-second reference to a product on a panel.

John Sullivan pointed out that the Research Committee had intended the document to be enabling rather than inhibiting of research, but also that public trust be sustained. Brenner added that the University had been able to respond to NIH efforts to impose policies by saying that a University policy is already in place. The Faculty Handbook requires some amount of disclosure. It is concerned both with disclosure of connections with outside sponsors and with the converse, implication that because of the researcher's connection with the University the research was done for the University, if in fact it was not.

Sam Krislov said that the NIH approach went too far and was too restrictive of transfer of technology. Potami added that the response to this is that to have the University take responsibility. Brenner said that the University should develop this document and give it to the NIH; government agencies tend not to be creative and can learn from us. Krislov observed that there may be instances where research could help industry, but agency funding could be jeopardized if agencies take the attitude that if company X is an interested party let them pay for it.

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John Thuenté cited instances in the Medical School where investigators had to state in the trial use patient consent form their connection with the company producing the medication. Brenner said that "all interested parties" would include patients in such trials. He added that if the study is only industry supported the current document gives the University control, but if not the document won't cover all bases.

Krislov said that an additional paragraph is needed on general principles.

2. Percentage of Interest in Funding Company

Potami said that a tripper point of 5% seems low, but much depends of the size of the company. Sullivan suggested deleting the amount and observed that people sometimes don't know exactly the amount of their stock. Potami added that they had considered using threshold words like "substantial" but these are hard to define. The trigger amount was just to show that there is interest. With agencies disclosure should not be in a sense that damages funding potential. The director may need to know, but it is of questionable relevance for peer review. If notification is made during peer review, he questioned when it the appropriate time: during the review or before the University signs off to accept the grant. He added that the NIH has a mandate to support small businesses, so disclosure of relationships to companies manufacturing a medical device, for example, could influence NIH choices. Krislov suggested asking agencies at which point they would prefer to have disclosures made. Potami and Thuenté said they will draft an inquiry and send it around.

Brenner said that the Research Executive Council has found that faculty seeking extra support within the University to finish projects can view money given as venture capital, which in the world is not free. Venture capitalists want something back for their investment and it is possible to negotiate the terms of their investment. Potami said that in the title of the document "industry" can be interpreted broadly, but in the body of the document the term "industry-sponsored" should be used. He added that there have not been many problems under the policy. From what investigators disclose to him it is hard to tell when further information is needed. Thuenté added that most are honest and understand the policy on patents, etc.

Brenner said that some groups, e.g., the Council of Judicial Affairs of the AMA bar from buying and selling stock during the period of involvement with a company. This would seem to be covered under the insider trading law, and covering it would be redundant. Disclosure of interest should be adequate. The idea is not to police investigators activities. If their interest changes during the course of their arrangement, they are obligated to disclose that fact. Krislov suggested amending the document to say that disclosure is needed "if substantial changes in the relationship to the company occur during the course of the grant." It was agreed that this section should be updated and expanded to include changes in interest.

3. Standing Committee

It was agreed that section 6 F should be changed since the standing committee doesn't exist as an entity. Potami said that there hasn't been an issue requiring it to convene. A subcommittee can be pulled together including members with particular appropriate expertise if the need arises. This section could be amended to say that a committee has to include certain categories, e.g., faculty, administrators, etc.

4. Executive Summary

Potami suggested that an executive summary is needed. John Yonas said that there is a major change in the tone of the disclosure concept as agencies grow more concerned and a corresponding need to demonstrate to them a willingness to take responsibility. The University needs to be able to say with confidence that there is no conflict of interest.

5. Use of University Name

Potami cited a need for a procedure to apply when actually transferring technology. Conflict arises not with the faculty member per se, but with the use of the University's name to get research money. There is disagreement over when the name should be used, and a written policy is needed. Krislov suggested that it should be written in such a way that Regent approval is required so that it will have the force of their support when it is necessary to say the name cannot be used. Potami pointed out, however, that Regents can be subject to lobbying from companies and regions. Decisions have to be made and parameters need to be set in this document.

6. Consultants

Brenner raised the question of possible conflict between serving as a consultant and having sponsorship with the same company. In some instances the consultant salary is compensation for work that is being done for the company anyway. Thuente said that consulting has to be separate work, even if it is on the same topic. Consultant work to company X and research as a faculty member at the University should be accounted separately. He added that the Medical School has asked for a statement from the company saying what would be done as a consultant. Potami added that some consultant agreements are bazaar and some faculty don't read them carefully enough. They think of it as just talk and not as technology transfer.

A question was asked of whether consultants automatically get copies of the policy. Brenner said that initially it is sent to all faculty and new faculty get it in a packet of orientation information. There is also a trigger when proposals are prepared and the investigator is referred to the document.

The meeting was adjourned at 3:00.

-- Catherine Winter

University of Minnesota