# UNIVERSITY OF MINNESOTA

done

*Academic Health Center*
*Office of the Provost*

*Box 501*
*420 Delaware Street S.E.*
*Minneapolis, MN 55455-0374*
*612-626-3700*
*Fax: 612-626-2111*
*Offices located at:*
*410 ChRc*
*426 Church Street S.E.*
*Minneapolis, MN 55455-0374*

March 12, 1997

Professor Judy Garrard
Chairperson, Provostal Faculty Consultative Committee
Academic Health Center
Box 729

Dear Professor Garrard:

I thought it might be useful to codify the items that are currently in consultation. My list includes:

- faculty indemnification
- access to student records
- the PIDP proposal

There are three other matters that need consultation:

- Research Service Organization
- AHC space plan
- Educational Service Organization

I will attach a copy of the current version of the RSO which has now been discussed at two sessions of the AHC Dean's Council. I would like it to now enter the consultation process.

Sincerely,

Frank B. Cerra, M.D.
Provost for the Academic Health Center
Professor of Surgery

Enclosure

FBC/bmg

cc: Mr. Terry L. Bock, Chief of Staff, Academic Health Center
Virginia Gray, Ph.D., Faculty Consultative Committee

| Post-it® Fax Note 7671 | Date | # of pages ▶ |
|---|---|---|
| To Judy Garrard | From Kathy Anderson | |
| Co./Dept. | Co. | |
| Phone # | Phone # | |
| Fax # 6-1629 | Fax # 6-2111 | |

APRIL 9, 1997

# MEETING NOTICE

**THE MEETING OF THE ACADEMIC HEALTH CENTER FACULTY CONSULTATIVE COMMITTEE AND THE UNIVERSITY SENATE HEALTH SCIENCES SENATORS (ACADEMIC HEALTH CENTER FACULTY ASSEMBLY) HAS BEEN CHANGED FROM APRIL 17 TO:**

**THURSDAY, MAY 1, 1997**
**12:00 - 1:30 P.M.**
**2571/2585 MOOS TOWER**

**Materials will be sent to you prior to the meeting.**

**If you are unable to attend, please inform the University Senate Office at the following e-mail address: senate@mailbox.mail.umn.edu**

UNIVERSITY OF MINNESOTA
Department of Laboratory Medicine and Pathology
Medical School
Box 609, 420 Delaware Street S.E.
Minneapolis, MN 55455-0385
(612) 626-0622
FAX: (612) 625-0617

# FAX COVER SHEET

DATE: April 10, 1997

# OF PAGES: 5
(Including this cover sheet)

---

**TO:** Vickie Courtney

**FAX #:** 5-4805

**Phone #:** 6-1609

---

**FROM:**
Leo Furcht
Department of Laboratory Medicine and Pathology
University of Minnesota Medical School
Box 609 UMHC
420 Delaware Street S.E.
Minneapolis, MN 55455-0385

---

Vickie:

Attached are the conclusion and list of appendices for the RSO report.

Jean Kurata
5-0932

P.S. Did you find a room for your meeting?

## 4.0 CONCLUSION

The objective of this review was to examine every step in the current process of applying for, receiving, monitoring and reporting on industry-sponsored research, and to recommend changes in these process steps, where needed, to improve and enhance the ability of faculty to market their research and service capabilities.

Our findings indicate that any plan to aid faculty in being more competitive in attracting industry-sponsored research must include the seamless coordination of all institutional and regulatory policies and procedures and approvals that affect corporate research. The plan must also include more responsive administrative, oversight, approval, and compliance monitoring services throughout the AHC.

We have recommended changes to the current process steps, and that a research service support office be developed to support investigators in navigating the new and improved process. There is little disagreement about the need for change on some scale. There is evidence from within and outside of the institution that real, meaningful improvements in our research management and compliance processes are essential.

It is clear that some within the AHC and the institution recognize the need for meaningful change. The questions now are: whose interests does the institution need to most protect? Can the interests of the institution be adequately supported and protected without supporting and protecting its constituent parts? Can the institution go beyond its inclination to consider only "who" often sacrificing "what" and "how"? Implementing the changes recommended will require direct, strong, committed leadership. The AHC has leaders who can effect the meaningful change needed.

## 5.0 APPENDICES

### 5.1 Conflict of Interest

**5.1.1 Federal Register: September 22, 1994**
Federal Register: (http://law.house.gov/7.htm)
Docket No. 93N-0445: Financial Disclosure by Clinical Investigators; Proposed Rule Department of Health and Human Services

**5.1.2 Federal Register: July 11, 1995 (Volume 60, Number 132)**
Objectivity in Research; Investigatory Financial Disclosure Policy; Final Rule and Notice

**5.1.3 Federal Register: July 11, 1995 (Volume 60, Number 132)**
Investigator Financial Disclosure Policy (NSF technical changes to investigator financial disclosure policy)

**5.1.4 Federal Register: March 5, 1996 (Volume 61, Number 44)**
Proposed Rules
Docket No. 93N-0445: Financial Disclosure by Clinical Investigators; Reopening of Comment Period and Notice of Meeting

**5.1.5 Federal Register: July 3, 1996 (Volume 61, Number 129)**
Frequently Asked Questions Concerning the Department of Health and Human Services Objectivity in Research Regulations and the National Science Foundation Investigator Financial Disclosure Policy

**5.1.6 University of Minnesota Board of Regents' Policy: Consulting and Outside Affiliations - Conflict of Interest**
(http://www.fpd.finop.umn.edu)

**5.1.7 University of Minnesota Board of Regents' Policy: Outside Consulting, Service Activities, and Other Work**
(http://www.ortta.umn.edu/policy/respolcy.htm)

**5.1.8 Current Academic Health Center Conflict Review Committee Application**

### 5.2 Academic/Research Misconduct

**5.2.1 Office of Research Integrity Advisory Document: Model Policy and Procedures for Responding to Allegations of Scientific Misconduct - April 1995**
(http://www.os.dhhs.gov/phs/ori/policy/policy.htm)

**5.2.2 University of Minnesota Board of Regents' Policy: Academic Misconduct**
(http://www.ortta.umn.edu/policy/respolcy.htm)

**5.2.3 Integrity and Misconduct in Reserach** (Report of the Commission on Research Integrity)
(http://os.dhhs.gov/phs/ori/policy/policy.htm)

## 5.3 Protection of Human Subjects

**5.3.1 FDA Information Sheets**
(http://www.fda.gov/oc/oha/toc.html)

**5.3.2 FDA Code of Federal Regulations (21 CFR Part...)**
(http://law.house.gov/cfr.htm)
50: Protection of Human Subjects/Informed Consent
56: Institutional Review Boards

**5.3.3 Federal Register: October 2, 1996 (Volume 61, Number 192)** Protection of Human Subjects; Informed Consent and Waiver of Informed Consent Requirements in Certain Emergency Research; Final Rules

**5.3.4 University of Minnesota Subjects Protection Program Committee Membership Lists**

**5.3.5 OPRR Protecting Human Research Subjects Guidebook**
(http://www.nih.gov/grants/oprr/oprr.htm)

**5.3.6 UM Research Subjects Protection Programs**
(http://www.ortta.umn.edu/subjects/subjects.htm)

**5.3.7 Current IRB Application Form, Continuing Review Form**

## 5.4 Protection of Animal Subjects

**5.4.1 FDA Code of Federal Regulations (21 CFR Part...)**
(http://law.house.gov/cfr.htm)
511: New Animal Drugs for Investigational Use
514: New Animal Drug Applications

**5.4.2 OPRR Animal Care Guidebook**
(http://www.nih.gov.80/grants/oprr/library_animal.htm)

**5.4.3 Animal Research Application Form B.A. 22**

**5.4.4 IACUC Executive Committee & Committee Panel Membership**

## 5.5 ORTTA

**5.5.1 GEMS and IDEA Grants Management Information**
(http://www.ortta.umn.edu/gems.htm)

**5.5.2 Current University of Minnesota Standard Contract/Agreement**
(http://www.ortta.umn.edu)

**5.5.3 ORTTA Policies and BA 23 (http://www.ortta.umn.edu)**

**5.5.4 Patents Technology Marketing Policy Manual**
(http://www.ortta.umn.edu/policy/respolcy.htm)

**5.5.5 Roles and Responsibilitities Document**
(http://test.finop.umn.edu/research/roles.html)

## 5.6 Department of Environmental Health and Safety

**5.6.1 Local, State, Federal Biohazard Regulations**
**5.6.2 UM Policies, Application Forms - Environmental Health and Safety**
**5.6.3 Regents' Policy on Research Involving Recombinant DNA and Hazardous Biological Materials**
(http://www.fpd.finop.umn.edu)

## 5.7 General Clinical Research Center
## Cancer Center

**5.7.1 General Clinical Research Center Application and Committee Membership**
**5.7.2 NIH Policy for GCRCs**
(http://www.ncrr.nih.gov/ncrr.prog/clcenter.htm)
**5.7.3 Cancer Center Protocol Review Process**
(http://www.cancer.umn.edu/)

## 5.8 General Appendices

**5.8.1 FDA Code of Federal Regulations (21 CFR Part...)**
(http://law.house.gov/cfr.htm)
312: Investigational New Drug Application (IND)
361: Prescription Drugs for Human Use Generally Recognized as Safe and Effective and not Misbranded: Drugs Used in Research
571: Food Additive Petitions
812: Investigational Device Exemptions
813: Investigational Exemptions for Intraocular Lenses
**5.8.2 FDA Form 1572**
**5.8.3 University of Minnesota Laboratory Certification and License Documents**
**5.8.4 Federal Register: October 7, 1996 (Volume 61, Number 195)** Medical Devices; Current Good Manufacturing Practice (GCMP) Final Rule; Quality System Regulation
(http://law.house.gov/7.htm)
**5.8.5 Articles Related to Patents and Technology Marketing**

a new infrastructure or a relatively simplified site on the Web that corporations can access easily. It was noted that these were two very different outcomes. On the one hand, there would be a very big office with many people, and on the other, there would be a system set up that was self-facilitating, with few people involved at the University level.
Mr. Furcht indicated that a Web site would be developed, and in fact a prototype already existed. It was suggested by the Committee that the name of the Report be Report be called Corporate Research Support Service

Section 1.2.1 Conflict Review Board Mr. Furcht noted that there were some committees that had more problems than others, notably the Conflict Review Committee. In some cases, proposals could be stuck somewhere for 60-90 days before action would be taken, and the closer the proposal was to the bottom of the pile, the longer it would take. Because there is no person to oversee this process, there has been no effort made to determine how the process would be streamlined. The Conflict Review Committee had greatly expanded beyond the Regent Policy governing research and in many investigators' estimations needs to be changed.

Section 1.2.3 Institutional Review Board: Human Subjects Committee It was noted that some corporations do not wish to work with the University because the timeline for completing the approval process is too long and complicated. The need was indicated for the University to be more user-friendly to corporations as well as its other constituents. Mr. Furcht noted that the AHC supports the University by a factor of at least 40% of their operation, but is not getting the number of professionals necessary to work with Patents and Licensing.

Section 1.2.5 ORTTA: Sponsored Projects Administration There seems to be a problem in the Sponsored Projects area with processing grants, particularly corporate grants, which Mr. Furcht didn't think had a high priority. He also indicated that in many cases the forms were not filled out correctly. There was also the problem of the time it takes to get a CUFs account set up. There are between 1000 - 2000 clinical trials being conducted at the University at any given time, but there is no overall coordination of these trials, no overall determination of prioritization, and virtually everything to do with the process is ad hoc.

1.3 Recommendations:

- to establish some parallel review process for the various elements;
- to establish performance criteria for each area;
- to integrate the areas in a more seamless fashion;
- to create an electronic tracking system;
- 1.3.1 disband the Conflict Review Committee
- 1.3.2 establish a new AHC-wide committee to review conflict of interest issues
- 1.3.3 establish a Business Development Office
- 1.3.4 enhance performance of Subject Protection Programs
- 1.3.5 improve and expedite contract review and negotiation
- 1.3.6 establish a Clinical Trials Coordinating Center

It was noted that the word "research" often was used synonymously with service, and that it was important to make the distinction between the actual research and the service, as they were not the same thing. Clarity was very important. It was also noted that the model was schizophrenic; there was nothing in the model that helped the research. Prof. Hamilton expressed the concern that there was the potential for a lack of coordination.

one member indicated

### 1.3.3 Business Development Office

It was asked if there would be a single reporting structure with different functions underneath it, or if there would be a lot of individual offices that would function independently. Mr. Furcht said that it was unclear as yet which would be the case, as the decision would have to be made at the Presidential level. ~~Prof. Bitterman~~ indicated that if there wasn't a comprehensive approach that related to the research and scholarship at the University, there would be a potential source of conflict. He said there was a need for a central coordinating point. There is the need for an office that corporations can reach. Mr. Furcht noted that there was a need to better coordinate, promote, and serve faculty. ORTTA needs a clear set of guidelines so people know what they can or cannot do.

Mr. Furcht noted several things. The playing field should be leveled so the AHC gets a fairer share of the royalties it is generating. Roughly half or more of the dollars generated by the AHC are going elsewhere to support activities that aren't generating nearly the type of income for the University. There is the need to expedite reviews and to have a set of readily available answers to questions corporations might have. Most corporations balk at the idea of indirect cost, and it was asked whether there was the need to address the issue of indirect cost with the corporations. There is the need to develop a system that allows for the development of a fully allocated budget, whereby the PI and the University both get the funds they need.

### 1.3.6 Clinical Trials Coordinating Center

NIH mandates that all cancer trials must be coordinated by a cancer center, and that all cancer trials be coordinated through this center, but it was asked why. The problem seemed to be coordination without domination with an intent to facilitate. There should be some sort of mechanism in place that coordinates trials and inform faculty of other trials that are currently being conducted. There was also concern as to the definition of the phrase "clinical trial." It was suggested that a keyword database be developed which will show any other trials that are being conducted on any given subject. It was noted that that IRB should be able to provide information on studies done on human subjects.

### Conclusion

Mr. Furcht reiterated that the objective of the report was to provide better services to the faculty and sponsors so that the University was more responsive administratively.

Prof. Hamilton indicated the Committee had a responsibility to communicate with other AHC faculty, and the question arose as to whether the issues should be taken ~~to the~~ up with President~~'s office~~. Yudof.

With no further business, the meeting was adjourned.