

AHC Finance & Planning

January 18, 2001

Minutes of the Meeting

These minutes reflect discussion and debate at a meeting of a committee of the University of Minnesota AHC Faculty Assembly; none of the comments, conclusions, or actions reported in these minutes represents the views of, nor are they binding on, the Assembly, the Administration, or the Board of Regents.

PRESENT: Dan Feeney (chair), Carol Wells, Elizabeth Nunnally Katie Dusenbery, Donna Brauer, Timothy Church

REGRETS: Michael Speidel

GUESTS: Mark Paller (Assistant VP for Research and Director, RSO), David Hagen (AHC Financial Management)

[In these minutes: Discussion with Dr. Paller and AHC Budget]

DISCUSSION WITH Dr. Mark Paller:

Professor Feeney welcomed Dr. Paller, called for introductions, and explained that the committee scheduled time with each the directors of the various AHC Centers and other departments outside of the college/school to talk about: 1) the center's mission; 2) the tangible and intangible value; 3) whether it is meeting its expectation and contributing to the overall AHC mission; 4) how the director would strengthen its role; 5) the demographics of the program; 6) the groups it primarily interacts with; 7) the groups outside of the AHC it interacts with; and 8) tentative plans for enlarging or shrinking the operation.

Dr. Paller began by prefacing that the RSO was created in the summer of 1997. The RSO's mission is dual; both highly service oriented and exists primarily to provide researchers in the AHC convenient an effective support for the preparation of research proposals, performance of clinical trials, management of research projects, and development of innovative technology. The RSO provides the private sector single-source access to AHC researchers and technology.

In the first year or so effort was spent on publicizing this service, with Dr. Paller meeting with groups in industry and city businesses. The bulk of the energy and resources are devoted to clinical trials and research support services for investigators. The RSO is organized as an internal service organization. The budget is divided up between the ISO and the portion of the work he does with the RSO.

Dr. Paller pointed out that the RSO's vision is important because it reflects some of the questions the committee raised about how service to faculty is provided. The RSO is very customer focused, although it has a judiciary responsibility to the University to make sure everything is done appropriately. The RSO wants to work on behalf of the investigators, faculty and its sponsors to shield them from the administrative obstacles that are found in a large institution.

Dr. Paller distributed copies of last year's annual report and said that the current annual report will be available within the next several weeks. He pointed out that the numbers would not be too different from the 1999 report.

Points from the 1999 annual report:

- 128 new proposals were reviewed; this year approximately 100 were reviewed.
- Process of services - there are two types of service 1) initiation services performed by research process managers who are responsible for writing the budget from the protocol and negotiating with the sponsor; prepare RIB application and other committee applications; and 2) the services of research coordinators who determine who is doing what in terms of FDA and other federal regulations.
- Currently the RSO is providing the "up front work" on approximately 2/3 of the protocols. The service of the RSO is great for those investigators who don't have enough work for a full time coordinator because the RSO coordinators will work on 5-6 protocols for 4-5 different investigators. (The coordinators get paid for the work they do on the specific protocol.) For example, at the end of 1999 there were 30 active trials for which the RSO had done all of the start up work and then turned over to the investigator's own employee or coordinator; there were 22 trials for which the RSO provided full service; and another 25 for which the RSO did the development work.
- For currently active projects, the time from application submission to IRB approval was 44 days (range 23-77) and

the time from submission of contracts to SPA until CUFS account number assignment was 42.3 days (range 6-76). The elapsed time from RSO receipt of a final protocol until study (ready for) initiation was 57 days. Prior to the RSO the time of receipt of the final protocol to the time that everything had been done was 151 days.

- For trials initiated since January 1, 2000, the average RSO turn-around time was 17 days. The time from IRB submission to IRB final approval was 67 days (up from 44 days the previous year). The average time from signature of the Proposal Routing form to assignment of CUFS number by Sponsored Projects Administration was 39 days (down from 42 days). However, the total elapsed time from receipt of protocol to assignment of a CUFS number was 109 days (up from 57).

One member opined that an approval should not take more than 30 days. Dr. Paller commented that innovative means of obtaining information should be considered, as long as long as it is within the regulations.

- The RSO works with all the AHC colleges however; Vet Med has set up its own clinical investigation center. The Medical School is the largest user of the RSO.
- Regular surveys are conducted to evaluate how the RSO is doing another indicator as to how well the RSO is doing is reflected by the number of repeat customers. There are at least three companies that will not place a study at the U of M if the RSO is not involved.
- Within the RSO there are 4 resource process managers; 4 clinical research coordinators; 1 secretary and 1 accountant. In addition, there is a person who works on a program that is sponsored and funded by Minnesota Technology Incorporated.
- While the RSO has grown rapidly over the past couple of years, there is no plan to expand in the near future.
- Some areas have reached capacity as opposed to the ability of the infrastructure to support growth. There are only so many clinical trials that can be done in a given area. There is potential for expanding activities by collaborating with investigators throughout the Fairview system but not at the Fairview/University Medical Center. Growth for growth sake is probably not appropriate, Dr. Paller noted.
- Members of the RSO staff have a system to keep track of their billable time. This data helps them develop their budget. There is always for potential for tension between faculty who want to get involved in everything and opportunities which scientifically may be great but financially may be border line. Costs of conducting trails are often calculated differently. For example, a private physician might only consider the marginal cost, while the RSO considers the full costs of doing a trial when calculating the budget. Also, Dr. Paller pointed out that a company will not pay the RSO until the first patient is enrolled. The company is not willing to pay for "talking." The indirect rate for a clinical trial is 23% and that is competitive with other institutions. Approximately \$100,000 from the AHC subsidizes the activities of the RSO. The goal is to not have the AHC subsidize the RSO. One member opined that if money eventually comes back to the AHC then it's not really subsidizing it, it is an investment.

Committee members thanked Dr. Paller for his time and information he provided. Dr. Paller invited members to email any additional questions to him, or to look at the website.

Ongoing discussion regarding the AHC budget compared to the rest of the University:

[The AHC F&P Committee plans to prepare a report that will show how the various units' budgets are being supported. The report should be ready for distribution in the later part of the spring semester. These minutes do not contain details of the discussion but rather points about the discussion.]

Elizabeth Nunnally and David Hagen, AHC Budget Office, distributed and walked the committee members through a document that provides information about the AHC's budget compared to that of the rest of the University. The areas under comparison include the Central Administration, the Professional Schools (Law School, Humphrey Institute and the Carlson School, although Carlson may not belong in this grouping) and all other schools.

Points of information:

- Compared to all other provosts schools the AHC receives about half of the state funding.
- All of the provosts schools can cover faculty salaries out of tuition dollars. The AHC needs to apply all tuition dollars plus sponsored funding as well as the state monies to cover faculty salaries.
- A pie chart showing all ranked faculty salaries by unit totaled \$230,757,392. The AHC comprises 37% or \$85,911,536. About \$36 million comes from the University of Minnesota Physicians (UMP). These monies are not really University dollars, it is clinical revenue generated by the faculty practice plans. The University is really functioning as an agent. Regardless, it was said, these are full time faculty on sight 100% of the time and part of the Medical School, the hospital and clinics. In essence, the University is getting \$110 million worth of value for \$85.9

million. Based on dollars of support, other schools are better supported for the FTE's they have to have to conduct their business than the AHC is. The AHC receives 12% funding from State dollars for faculty salaries.

- The question the committee would like to address is how big the AHC budget is compared to the other schools; how much of it is self-supporting versus how much of it is not.
- Committee members then spent some time discussing the "added value" of outside consulting done by faculty and whether it is considered as part of the salary structure.
- Committee members will continue working through the document at its upcoming meetings. In April, Professor Feeney has indicated he will make a report to the Senate Committee on Finance & Planning.

The meeting was adjourned at 6:00 p.m.

Vickie Courtney