

APRIL 3, 2002

GENERAL FACULTY COMMITTEE MEETING MINUTES

In attendance: Haddad, Woitowicz, Ten Eick, Decker, Vohra, Elson, Garrison, Farbman, Halperin, Jennings, Eagly, Whittington

Institutional Review Board (IRB) - Clinical Research

Institutional Review Board representatives Dennis West and Carol Nielson presented an overview of issues and concerns facing the Medical School's clinical research. The main concern is that on any given day they are at risk of being shut down by the federal government, so IBR is primarily trying to grasp and enforce continually changing compliance issues that are being added to the IRB's responsibilities by the federal agencies. Non-compliance with the government could cost the University as much as \$ 20,000,000 if fines are levied for infractions that shuts down clinical research at the University.

These are some of the other issues the Institutional Review Board is faced with:

Federal regulatory agencies: OHRB, which deals with the ethics side of human research, and the FDA, which deals with the drugs and devices side. Both influence IRB actions on a daily basis.

Patients: Privacy issues of patients and getting appropriate consent of patient before the clinical trials commence are two major issues that have to be addressed. Patients are coming back to the University with complaints and/or patients are complaining directly to the regulatory agencies about their treatment, care, and the nature of the trial that they have been enrolled into. One of the ways research institutions are monitored is by the number of complaints (which the institutions are unaware of) they receive. Better more proactive communications are needed to eliminate this problem.

Staff: Shortage of staff is currently a tremendous issue. There are a total of 12 staff at Northwestern (compared to U of I at 28); members overloaded with all the projects (635 in Evanston and 2563 in Chicago) coming into the IRBs. Increase in staff is greatly needed. A suggestion was made to consider hiring a clinical science editor to aid the faculty in developing the appropriate language for research proposals.

Investigators, faculty and key personnel: All complain of project overload. Individual faculty members are too subjective on projects. Faculty community is not diligent in providing feedback and critical information regarding projects. There is inappropriate attendance at federally-required quorum to discuss projects. Presently, only have 5 medical IRB committee panels.

Institutional Problems: It is difficult to keep up with changes, and is especially difficult to educate faculty of these changes. The local (academic) IRB current turnaround time for each proposal is approximately 70 days, compared to a centralized (privatized) IRB turnaround time of 35 days. Academia cannot compete with privatized organizations because they have more staff and are more specialized, having greater knowledge of what to submit.

The Institutional Review Board has been and still is proactive in combating the issues that face them. **These are some of the actions IRB has taken to improve compliance levels:**

1. An objective of IRB is to be aware of audit points when another institution is shut down.
2. Invested \$160,000 in a new database that will help process to run with a higher degree of precision and ease.
3. Purchased a training website for project investigators and key personnel to aid in preparing new proposals
4. Requested extra personnel but got turned down

Final thoughts and suggestions

Representatives were asked to draft a list of issues, concerns and worst-case scenarios they would like to have addressed. GFC members agreed to establish a sub-committee to work with IRB to minimize potential federal intervention.

Institutional Review Board (IRB) - Social and Behavioral Research

Social Science and Behavioral Studies IRB representative Gary Fine presented an overview of the program. Most cases are not problematic nor are they considered unethical but issues do still exist. Resources or lack thereof, is among the biggest problems faced by the Behavioral and Social Science IRB and are greatly needed as the level of research expands.

Here is a brief synopsis of other major issues and concerns.

Structural: In the past, there were three to four IRB panels where as currently there is only one with a likely addition of another.

Informal consent: How much the subject should be informed about the study requires further clarification.

Research with Children: Time and time again this type of research proves to be very difficult due to the need to have explicit approval of the parents before the subject can be used.

Paper overload: Offices are being flooded with proposals, expedited projects and other paper documents. Ideally, IBR would like to have periodical reviews taken out of the process to lighten the load a bit.

Final thoughts and suggestions

Gary Fine was asked to draft a list of issues, concerns and worst-case scenarios he would like to have addressed.

University Faculty Reappointment, Promotion, Tenure and Dismissal Appeals Panel (UFRPTDAP)

Representative Martin Mueller gave a brief overview of UFRPTDAP. This elected committee hears appeals arising from the tenure process and the disciplinary process. Approximately one or two cases are heard each year. The quality and judgments of the committee members are good but other questions and concerns have been raised committee selection and function.

These are some of the issues addressed:

Election process: The election of the hearing panels is currently being done by the provost who ultimately makes the final decision on the outcome of the case. This election process, which simply does not make sense, raises questions of fairness and conflict of interest. An alternative to this election would be to have GFC take over the process of making the determination of whether a case should be heard and then appoint a panel.

Disciplinary Process: Since the committee deals overwhelmingly with tenure cases it would be ideal for disciplinary cases not to be handled by UFRPTDAP. Why mix the two?

Case Evidence: Since the process leading up to denial, termination or disciplinary actions is, itself under scrutiny, evidence in cases is kept confidential and is not presented to the UFRPTDAP committee. Faculty want to see the evidence and the administration wants to protect it. How can good decisions be made without all the facts?

Final thoughts and suggestions

GFC members will discuss the linkage between GFC and UFRPTDAP. One of the GFC members suggested that the chair of UFRPTDAP sit in on GFC meetings. A suggestion was made to put GFC on the UFRPTDAP homepage.

Conclusion of meeting:

Discussion of issues on student contact hours raised by Laura Wilber is postponed until the May 1st meeting.

Medical School will talk about financial planning at the May 1st meeting.

Posting GFC issues on web is ideal.