Human Subjects – Post-Approval Monitoring and Auditing of Research Activities

The University of Washington, like most institutions, has an Institutional Review Board (IRB) that reviews research activities involving human subjects. The IRB reviews human subjects procedures in research activities at the time that research proposals are submitted to funding agencies, but does not currently conduct any post-approval reviews unless there are specific complaints from human subjects. Last year a task force was established to evaluate whether the current review process is adequate in terms of liability and risk management. In the context of a growing national debate and prevalence of lawsuits concerning the conduct of researchers, the task force recommended extending protections to human subjects with a post-approval monitoring and auditing compliance program.

The UW Office of Research asked Daglish, an attorney with many years of experience in issues of compliance, human subjects, and health care, to make specific recommendations as to how UW might carry out a post-approval program. He presented his report to FCR members.

In order to evaluate the conduct of researchers, Daglish said, one must first consider whether rules of conduct have been clearly articulated and widely communicated. In his report he recommended that UW implement education and training mechanisms before post-approval monitoring or auditing took place. Several FCR members expressed concern that some faculty members are currently unaware of proper protocol involving human subjects. They agreed that an education campaign of some kind is necessary.

Daglish continued by detailing two ways of evaluating researchers’ conduct in a post-approval program: monitoring and auditing. Daglish explained that a monitoring system could include:

1) literature reviews
2) whistle-blower encouragement and protection programs
3) hotlines to handle complaints and a means of following through on complaints
4) investigator monitoring
5) a means of monitoring the monitors
6) requirements of formal, written attestations from investigators and institutions
7) informed consent monitors
8) requirements that negative results be published
9) assessment of subject satisfaction, and/or
10) researcher ID requirements.

An auditing program, Daglish explained, could be conducted selectively based on 1) complaints from human subjects and 2) the level of risk involved in particular research activities. Daglish's report recommended that UW establish an audit protocol to ensure fairness, thoroughness, and appropriateness of the auditing process.
Some members were very concerned about a "one-size-fits-all" approach to post-approval monitoring and fears of an overly large burden placed on University resources and personnel. While they recognized the serious need for rigor in the approval process of research activities involving human subjects, they felt that the current administrative procedures are already too large of a burden for many faculty members, especially those without support staff, to bear. Daglish and Parks emphasized that post-approval programs could be "scalable" depending on the level of risk, and that many of the recommended components of the monitoring program are actually not terribly expensive or difficult to implement (e.g. a hotline, a website, etc.).

Perrin asked if other research institutions were considering implementing programs such as this one and if so, whether UW could join forces with some of those institutions. Daglish said that all major research institutions are facing this same issue and suggested that UW should indeed be working with other institutions with the goal of guiding Federal regulations before Federal regulations inevitably guide them. There is also a possibility, according to Daglish, that the Federal government will begin an accreditation program for IRB's at research institutions in the near future.

Parks said that while the administration recognizes the need to act on this issue, it is not committed one particular post-approval method over another. Next year discussions will continue, in which Parks said FCR would be involved.

**Updates on Issues Previously Discussed by FCR**

**Online Library**

As was discussed at the April 12 meeting, Bothwell reported that he brought up the issue of hosting a panel forum on online libraries with the Faculty Senate leadership. Brad Holt, the 2001-02 Faculty Senate Chair, said he could help facilitate such a panel forum in 2001-02.

**UW Consulting Corporation**

Regretfully, Bothwell told the Council that Ewart has relinquished his efforts to create a UW Consulting Corporation that would have allowed UW faculty to consult in compliance with State ethics laws. He said the Ewart encountered too much resistance within the University and became discouraged. Bothwell hoped that if another faculty member in the Council wished to pick up the cause, s/he would do so.

**Copyright Policy**

Parks told the Council that he has withdrawn all of the proposed revisions to the copyright policy except for one, non-controversial portion regarding clarification of copyrights and the use of University resources. Parks plans to submit the single revision to the President as an Executive Order, which FCR, as part of the standard approval process, will have an opportunity to review.

*Meeting adjourned at 1:10 p.m.; minutes by Katherine Wimble, Recorder.*