

**TO:** Hans Ostrom, Chair Faculty Senate  
**FROM:** Ray Preiss, Chair Institutional Review Board  
**DATE:** May 5, 2003  
**RE:** End-of-year Report

The Institutional Review Board (IRB) entered the 2002-2003 academic year with the charges of implementing the Puget Sound guidelines for protecting human subjects (monitoring and reviewing protocols), maintaining a web presence, conducting outreach, and considering changes in policies. I am pleased to report considerable progress on these issues, as this report documents.

### **On-going Charge to the IRB**

Considering our activities this year, we have diligently pursued two standing charges from the Faculty Senate: (a) The routine activities of monitoring protocols and (b) Maintaining our presence on the World Wide Web.

**Routine activities:** As a Standing Committee, the IRB is tasked with monitoring protocols, maintaining a system for managing records, and deliberating on policy questions. During the 2002-2003 academic year, most of our time was devoted to evaluating protocols. We received 17 protocols and formally approved 6 research projects and authorized two modifications of existing protocols. It is noteworthy that 11 protocols will be processed at our May 7, 2003 meeting. We have not seen this late surge in submissions before and we are monitoring the situation to determine if this is a trend.

All deliberations are posted in IRB Committee Minutes. Because the Chair is often contacted with questions related to these deliberations, the Chair's Notebook tracks all protocols. The Associate Deans Office is the repository of records, protocols, and final reports.

**Presence on the World Wide Web:** The IRB established a presence on the World Wide Web in the Summer of 1998 ([www.ups.edu/dean/irb/](http://www.ups.edu/dean/irb/)). Documents posted on the IRB Web Page include the revised IRB Guidelines document and various forms for protocol preparation. These forms can be downloaded. In addition, the Web Page includes the IRB policy on the Ethical Care and Use of Animals that was adopted in the Spring of 1998. Based upon work three years ago, the IRB provides a link to the University of Puget Sound IACUC. Forms and procedures are now available on the IACUC Web Page.

We continue to add documents and links to resources that may assist student and faculty researchers. Currently we post links to the National Institutes of Health Office of Extra-mural Research, as well as an array of on-line resources useful to active researchers and students enrolled in research methods courses or engaged in independent research projects. In addition, the page now includes a description of the activities of the IRB, a roster of IRB members and department IRB designates, scheduled IRB meetings, and a list of frequently asked questions.

Informal feedback regarding the Web Page continues to be favorable. The Web Page is consulted regularly for forms and procedures, to resolve questions related to individual research projects, and as a guide for protocol preparation. We will continue to refine the Web Page as the needs of our students and faculty evolve. We are pleased to report that the Web Page has increased the visibility of the IRB and provides a useful resource.

One difficulty that occurred this year involved a dropped protocol. A modified protocol was submitted that was nearly identical to the original protocol. I inadvertently filed the protocol as "approved" although it had not been reviewed. Three weeks later, a senior member of the department enthusiastically brought the error to my attention. We have repaired the web forms to correct this error. First, we added a "date" line that will differentiate between similar protocols.

Second, we changed the system for logging protocols at the Associate Deans' Office. When a protocol is submitted, an email is sent to the primary investigator notifying him or her of the IRB tracking number. Investigators are now asked to contact the Associate Dean if they have not received an email within 24 hours.

### **Outreach to the University Community**

This year the IRB continued its efforts on the area of outreach and education. We have developed a survey on the use of human subjects. Next year the survey will be sent to all IRB designates who will distribute the information to departmental colleagues. We will use this information in personal contacts with individuals expressing interest in, or concerns about, research involving human subjects. This issue is important if we are to avoid unauthorized use of human subjects. We discovered, for example, that one department erroneously thought that a "blanket exemption" was in effect for their student research projects. The IRB contacted the department designate, exchanged correspondences with the professors, and received assurances that this practice had been terminated. The survey is designed to help identify other areas where intervention may be needed.

### **Proactive Monitoring of Protocols**

The IRB was charged by the Faculty Senate to consider developing guidelines for oversight of ongoing research. Some members believe that "IRB Police" are not warranted. Others note that we have inadequate resources for this task. We estimate that we would need two release units each semester to conduct on site visits. A standardized report format is not feasible, as department norms dictate this content. We continue to discuss guidelines and consider ways to ensure confidentiality and consent.

### **Upcoming Agenda Items**

Based upon the progress made in addressing the charges given by the Faculty Senate this year, the IRB has identified the following goals for the next academic year:

- Continue to monitor protocols and maintain and manage records for research involving human subjects.
- Upgrade and refine the IRB Web Page with information appropriate for student and faculty researchers.
- Distribute a campus survey as part of a system of outreach and education that promotes IRB review as an integral part of the research planning process.
- Continue developing a system for monitoring ongoing research.

I owe special thanks to IRB members for hard work at inconvenient hours: Mirelle Cohen, Patrick Coogan (Community Representative), Lisa Ferrari, John Finney, Judith Kay, Yvonne Swinth, Tom Wells, and John Woodward (Secretary).