The University of
Puget Sound

Office Memorandum

TO: William Beardsley, Chair
Faculty Senate

FROM: Ray Preiss, Chair
Institutional Review Board

DATE: May 6, 2004

RE: IRB End-of-year Report

The Institutional Review Board (IRB) entered the 2003-2004 Academic Year with three charges: (1) implementing the Puget Sound guidelines for protecting human subjects (monitoring and reviewing protocols), (2) updating and refining the IRB presence on the web, and (3) establishing a system for insuring that protocols accurately reflect laboratory and field procedures. I am pleased to report considerable progress on these issues, as this report documents. At the close of this end-of-year report, I present issues the Faculty Senate may consider when crafting charges for the 2004-2005 IRB.

Implementing the Puget Sound Guidelines for Protecting Human Subjects

We have diligently pursued our primary activities of receiving and assessing protocols submitted by Puget Sound faculty and students. We do, from time to time, process protocols originating from other universities (two protocols in this category were reviewed this year). We allow this to occur so that our university can be known as a reliable and cooperative partner in the search for knowledge. Also, we understand the importance to Puget Sound faculty of reciprocal access to subjects on other campuses. We allow protocols from other universities to be initiated only after full IRB review. We do not allow private parties or commercial interests to use University of Puget Sound human subjects in experimental research.

An important aspect of IRB duties involves monitoring protocols, maintaining a system for managing records, and deliberating on policy questions. During the 2003-2004 Academic Year, most of our time was devoted to evaluating protocols. We received and formally approved 21 research projects. This represents a 16% increase in submitted protocols from the previous year. Many protocols require multiple IRB deliberations. In six cases, protocols were approved pending minor modifications. Three protocols were sent back to investigators with questions and concerns. 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.

In the previous paragraph, I noted that deliberation regarding policy questions is an essential part of IRB responsibilities. In the past, these deliberations involved issues of vulnerable populations (e.g., children, elderly, psychological distress, and patients experiencing pain during physical rehabilitation regimens). We have offered case-by-case reviews addressing issues such as non-English speaking immigrants, physically and emotionally abused children, and student substance abuse. In these deliberations, the IRB aspires to promote knowledge acquisition while protecting human subjects. We have devised clear policies on subject anonymity, informed consent, coercion, deception, acceptable discomfort and pain levels, and sensitive activities (crime, sexuality, substance abuse, etc.). I am pleased to report that IRB deliberations continue address important issues vital to protecting human subjects.

There is an emerging consensus on the IRB that experiments must address significant questions to gain a favorable review decision. Previously, the IRB had only ruled on safety and confidentiality concerns for "minimal risk" protocols and theoretical or applied benefits for "moderate risk" and "high risk" protocols. The IRB has never processed a protocol designated "high risk." The IRB is now discussing including theoretical and applied benefits to "minimal risk" protocols as well. The idea here is that even innocuous methods impose on subjects' time, energy, and intellect. Good reasons must be provided to justify these impositions.

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/). 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. A charge to the IACUC during the 2001-2002 academic year was to place its forms and procedures on this Web Page. The IACUC now has its own Web Page, guidelines, documents, and minutes.

We continue to add documents and links to resources that may assist student and faculty researchers. The IRB first established a presence on the World Wide Web in the Summer of 1998. 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. We recognize, however, that some links have been deactivated, that the IRB pages are not easy to navigate, and that first-time users can be baffled by our check lists and procedures. We have made plans to offer model protocols and simplified instructions for novice student researchers. These efforts are on-going.

Insuring that Protocols Accurately Reflect Laboratory and Field Procedures

The final charge from the Faculty Senate for AY 2003-2004 involved proactively monitoring protocols. The IRB has discussed this issue at length. We have developed a framework where student protocols are to be field checked by the designated Faculty Advisor. Upon approval by the IRB Designate, the student, operating under the Advisor's directions initiates the protocol.

Proactively monitoring faculty protocols is more complex. The IRB has visited and examined facilities used to store confidential information and some laboratories. To date, we have not been able to be on the premises when data were being collected. The IRB does not have the staff or resources to systematically observe laboratory or field methods.

On-Going Concerns

In response to my 2002-2003 report to the Faculty Senate, one Senate member opined that the IRB was slow in rendering decisions and that student research projects were unnecessarily delayed by IRB review. In my oral remarks last year, I defended the time used to ensure effective review. I am pleased to report that during the 2003-2004AY no concerns have reached my desk regarding slow turnaround time or inconveniences attributed to delays. I take this as evidence that the IRB is doing its job in a responsive manner.

In my 2002-2003 Annual Report, I asked the Faculty Senate to consider the workload of IRB members. I again make this request. In addition to reviewing protocols, the IRB is being asked to work over the summer, to build Web resources, and to be on-site while data are being collected. We do not have a Compliance Officer (as Federal regulations specify), a budget, or support staff. I ask the Faculty Senate to discuss the recommendation that the Chair of the IRB be allowed a one unit release from teaching duties to cope with these burdens.

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:

1. Continue to monitor protocols and maintain and manage records for research involving human subjects.
2. Upgrade and refine the IRB Web Page with information appropriate for student and faculty researchers.
3. Develop a system for ensuring timely review of protocols originating during the summer months.
4. Arrange for consultations with a certified Compliance Officer to ensure that the IRB is current with evolving case law and Federal mandates.

As I end my service as Chair of the IRB and embark on a sabbatical, I would like to thank the Faculty Senate for your oversight. I owe special thanks to IRB members for hard work at inconvenient hours: Roger Allen (Secretary), Patrick Coogan (Community Representative), John Finney, Robin Foster, Dash Goodman