

**Institutional Review Board
End-of-Year Report
to
Faculty Senate
April 30, 1997**

The Institutional Review Board (IRB) entered the 1996-1997 academic year charged with 1) developing a system to insure that research protocols involving the use of body fluids followed specific guidelines for safe handling and disposal, 2) revising and simplifying the various forms used in the protocol review process, 3) developing a formal outreach program to educate departments about the policies and procedures of the IRB, and 4) drafting guidelines for faculty or students interested in conducting research using animals. This report will summarize the routine activities of the IRB as well as the board's progress in meeting each of these charges.

Routine Activities

As a Standing Committee, the IRB is responsible for monitoring protocols, maintaining and managing records and drafting and considering policy for issues related to the protection of human subjects. The board evaluated and formally approved 19 new protocols and granted a renewal of one protocol during the 1996-1997 academic year. Nine protocols that were submitted to the full board met the criteria for expedited review and were approved by the Chair on behalf of the board. Individual departmental designates reported that they approved an additional 88 protocols which met either exempt or expedited status according to IRB Guidelines. Information regarding the approval of all protocols reviewed by the full board is kept on file in the Office of the Associate Deans. Information regarding protocols that were approved by departmental designates is housed in the respective department offices.

Charge #1: Process for Protocols Involving the Use of Body Fluids

The IRB discussed the issue of personal safety of both researchers and participants involved in studies involving the use of human body fluids and contacted various departments to learn how they were handling body fluids. Instead of drafting another policy addressing the safe handling of body fluids specifically for research projects, the board elected to require that students and faculty members follow the University's existing policy on the subject which is published in a document entitled, "University of Puget Sound Blood borne Pathogen Exposure Control Plan and Policy". Individuals submitting protocols in which there is any risk of coming in contact with body fluids will be directed in the revised version of the IRB Guidelines document (see below) to refer to this policy. In order to ensure that this policy is followed, all protocols involving body fluids in any amount will be subject to full board review rather than expedited review.

Charge #2: Revision and Simplification of Process/Forms for Protocol Submission

The original guidelines drafted in 1993 during the creation of the Institutional Review Board were intended to outline the regulations concerning the protection of human subjects and to guide faculty or student researchers through the process for submitting protocols. Although this document met the needs of the IRB initially, it was somewhat generic and not geared specifically to the types of research being conducted at the

University of Puget Sound. Individuals and departments who submit protocols regularly have found portions of the document to be cumbersome, vague and sometimes difficult to follow.

In order to address this, a subcommittee is in the process of revising and simplifying the guidelines and process used for the submission of research protocols in order to make them easier for students and faculty members to understand and follow. This has involved a restructuring of the present document such that all information pertaining to protocol preparation is now placed together while definitions, examples of various forms and other materials will now appear in an appendix.

Wording in the document has been changed to clarify important concepts regarding the determination of which type of review is most appropriate for a particular protocol. In addition, the criteria for expedited and full board review have been clarified and made more specific. The various forms used in the protocol submission process have also been restructured to make them easier to use.

The revisions to the document as described above have been made and will be distributed to the rest of the board for review before the first meeting of the Fall 1997 semester. Once approved by the full board, the revised guidelines document will be distributed to all departments and the guidelines and templates of the various forms will be put on an IRB page on the World Wide Web.

Charge #3: Development of a Formal Outreach Program

The IRB has been investigating ways to develop a formal mechanism for disseminating information pertaining to the role of the IRB and the protection of human subjects. A subcommittee has identified the following areas that might be covered in such an outreach program: 1) Education regarding the mission of the IRB including federal regulations and university policies and how those standards are being applied at the University of Puget Sound. 2) Development of educational materials regarding issues related to student and faculty research and obtaining and maintaining a collection of resources pertaining to specific issues related to the protection of human subjects in different types of research.

In order to determine the specific needs of the University in terms of the type of education provided in such an outreach program, the IRB has drafted and sent a survey to each department. The survey which is a revision of a survey originally sent to departments in 1992, is designed to determine the types of research activities involving human subjects being conducted at the University of Puget Sound, to assess departmental awareness of the policies governing research using human subjects and to discern the ways in which researchers are being informed about policies and procedures related to the use of human subjects in research. The results of this survey are presently being compiled and will be used to guide the structure and development of an education program.

Once the education program has been established, the board plans to conduct a series of briefings to the university community. These briefings may take place in individual department meetings at the request of departments, as part of courses in which research projects are required or with departmental designates as a group. In addition to face-to-face meetings with departments or classes interested in the function of the IRB, the subcommittee also plans to use an IRB web page as a comprehensive resource for researchers. Such a page would include information such as the Guidelines document,

flow charts for routing protocols, a description of the protocol review process, deadlines for submission of protocols and IRB meeting dates.

The development of a formal outreach program looks to be a dynamic and ongoing process rather than a one time activity. The tasks outlined above will entail considerable background work in terms of drafting a presentation that can be made to interested parties, writing and maintaining a page on the World Wide Web, gathering resource materials and training IRB members to make these educational presentations.

Charge #4: Guidelines for Conducting Animal Research

Although the Institutional Review Board is primarily involved with the protection of human subjects in research, it has also been asked to develop a process for ensuring the humane treatment and handling of animals in research. A preliminary investigation into the federal regulations governing animal research revealed that the process of establishing a policy would be at least as complex as the process for the protection of human subjects. Furthermore, the regulations stipulate that special facilities must to be constructed and maintained for the purposes of handling and housing

the animals and that a veterinarian must be hired to act as a consultant for anyone involved in animal research. In addition, periodic reviews by the division of the Department of Agriculture responsible for governing animal research must also be conducted.

Before drafting a policy on animal research, the IRB polled individual faculty members and departments to determine who was presently conducting or interested in conducting animal research. The results of this informal poll suggested that no one on campus is currently engaged in research using animals. The only species of animals that might fall into a category that would need to be protected by such a policy are rats in the Psychology Department. Since these animals are used primarily for classroom teaching purposes rather than for research, it is unclear at this time as to whether a policy governing their care and use other than the guidelines provided by the American Psychological Association is necessary.

Given that no one on campus is currently involved in research involving the use of animals, the IRB has determined that it would not be time or cost-effective to draft and implement a specific policy at this time. In order to address the possibility that faculty or students might wish to conduct research involving the use of animals in the future, the IRB has made a collaborative arrangement with Madigan Army Medical Center (MAMC) who already has a formal process and appropriate facilities for reviewing and conducting animal research.

Simply stated, anyone from the University of Puget Sound who is interested in doing animal research would be directed to contact a researcher from MAMC with similar interests. The two parties would then collaborate to draft a protocol which would be submitted to MAMC's animal research board for review and approval. This is acceptable practice as long as someone from Madigan is designated as a co-investigator on the protocol.

This proposal, although not the same as having a formal animal research review board, does allow UPS faculty and students who are interested in this type of research an opportunity to do so. The proposal describing this arrangement and the process will be distributed to the university community at the same time as the revised guidelines document in the Fall of 1997.

Goals/Agenda Items for AY 1997-1998

Based on 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) Finalize and distribute the revised IRB Guidelines document to all departments.
Draft and distribute the proposal regarding the collaboration with Madigan Army Medical Center for faculty and students who are interested in doing animal research.
- 2) Analyze and use the results of the departmental survey to structure a formal outreach program for interested parties.

Prepare a standard education presentation describing the mandates and obligations of individuals conducting research using human subjects and the role and function of the IRB at UPS.
- 3) Apply to the Dean for a release unit to enable the IRB to develop materials for an outreach program and request a budget for acquiring books and resources on issues related to human subjects research.

The person receiving such a release unit would be responsible for developing an IRB page on the World Wide Web, searching for models and documents used by other university IRBs, locating appropriate books and other media that could become part of a resource library and directing the

effort of writing a formal presentation that could be given to interested parties by any member of the IRB.

Respectfully submitted,

Ann M. Ekes
Chair
Institutional Review Board