

**Institutional Review Board
End-of-Year Report
to
Faculty Senate
April 27, 1998**

The Institutional Review Board (IRB) entered the 1997-1998 academic year charged with 1) finalizing and distributing the revised IRB Guidelines for all departments, 2) drafting a proposal/policy for faculty and students who are interested in doing animal research, 3) using the results of the departmental survey to structure a formal outreach program for interested parties and preparing a standard education presentation describing the mandates and obligations of individuals conducting research using human subjects and the role of the IRB at UPS. 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 research 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 27 new protocols and granted a renewal of one protocol during the 1997-1998 academic year. Individual department designates reported that they approved an additional 55 protocols which met either exempt or expedited status according to the 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 reviewed and approved by departmental designates is housed in the respective department offices.

Charge #1: Finalize Revised Guidelines Document

The original guidelines document drafted in 1993 during the creation of the Institutional Review Board underwent significant revision this year and resulted in a revised document which was adopted by the board this spring. The revised document is now ready for distribution to department designates and will be placed on an IRB Web Page to be created in the near future.

Charge #2: Draft Policy for Use of Non human Animals in 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. An investigation into the federal regulations governing animal research revealed that the process of establishing an Institutional Animal Care and Use Committee (IACUC) at the University of Puget Sound would be at least as complex as the process for ensuring the protection of human subjects. Furthermore, the regulations stipulate that special facilities must 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.

As part of its investigation into this matter, the IRB polled individual faculty members and departments to determine who was presently either conducting planning on 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 the rats used by faculty and students in the Psychology Department. Since these animals are used primarily for classroom teaching purposes rather than for research, the Psychology Department appears to be in compliance by abiding by the regulations stipulated in the American Psychological Association's Guidelines for Ethical Conduct in the Care and Use of Animals.

Given that no one on campus is currently involved in research involving the use of animals, the IRB determined that it would not be appropriate to recommend that the university expend the resources to establish its own IACUC at this time. In order to address the possibility that faculty or students might wish to conduct non human animal research in the future, the IRB sought ways to allow for this while ensuring the appropriate care and use of the animals. The board investigated the possibility of having faculty or students from Puget Sound who are interested in doing non human animal research collaborate with individuals from institutions that have an IACUC already in place which would ensure that the research was being conducted in accordance with federal, State and local regulations. The response was favorable, leading the board to conclude that it was possible and practical for individuals from Puget Sound to collaborate with individuals from one of these other institutions.

A policy concerning the ethical care and use of animals in research at the University of Puget Sound was drafted and adopted by the IRB for dissemination to the University Community in the near future. A copy of the policy is attached to this report.

Charge #3: Outreach Program and Education Regarding the IRB

The IRB used the results of a department survey conducted during the Spring of 1997 to determine the need for an outreach program for individuals or departments interested in learning more about the IRB. The survey revealed that those departments who routinely conduct research using human subjects are familiar with the role and function of the IRB, however, those departments who conduct research infrequently may not be as familiar with the process. The survey also revealed that the greatest need for information was from the department designates who act on behalf of the full board to review and approve protocols which fall into either the exempt or expedited categories of review.

Rather than establishing a comprehensive outreach and standard education program which targets the entire University Community, the board decided to concentrate its efforts on providing information to department designates and faculty members or departments who wish to learn more about the role and function of the IRB. To that end, the IRB is establishing a page on the World Wide Web which will include the following:

- 1) The revised IRB Guidelines document including forms which may be downloaded.
- 2) A list of frequently asked questions about the process for submitting protocols as well as questions that department designates may have concerning the protocol review process.
- 3) A flow chart outlining the protocol review process and timelines for submitting protocols for review.
- 4) A list of resources to assist faculty or students in understanding the moral, ethical and legal issues surrounding the protection of human subjects in research.
- 5) A list of department designates and members of the IRB who can be contacted with questions concerning protocol preparation or submission or the protocol review process.
- 6) The policy concerning the ethical care and use of animals in research.

The IRB has also acquired an informational videotape and manual from the National Institutes of Health (NIH) that chronicles the history of the evolution of institutional review boards and describes the federal regulations regarding the protection of human subjects. These materials are available to interested parties in the Collins Memorial Library.

Goals/Agenda Items for AY 1998-1999

Based on the progress made in addressing the charges given by the Faculty Senate this year, the Institutional Review Board 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) Establish and maintain a presence on the World Wide Web as outlined in charge #3 above.
- 3) Implement the policy concerning the ethical care and use of animals in research and discuss the need for further intervention on the part of the Institutional Review Board.

Respectfully submitted,

Ann M. Wilson
Chair
Institutional Review Board

University of Puget Sound
Ethical Care and Use of Animals in Research
1998

Research involving the use of non human animals must ensure their ethical and sensitive care and must be undertaken with a clear articulated scientific purpose. Researchers who are involved in animal research must be familiar with the Federal Regulations and guidelines set forth by the U.S. Department of Agriculture Animal Welfare Standards document (*Federal Register*, 1991, February 15), policies set forth by the Public Health Service as well as state and local ordinances involving the appropriate and humane treatment of non human animals.

All protocols for research using non human animals must be reviewed by an appropriate animal care committee such as an institutional animal care and use committee (IACUC) to ensure that the procedures outlined are in accordance with the federal regulations set forth by the U.S. Department of Agriculture as well as State and local ordinances regarding the humane treatment of animals. Since the University of Puget Sound does not have its own IACUC, individuals who are interested conducting research with animals must locate an institution that has such a board or review process and establish a collaborative relationship with an individual or group from that institution. Once appropriate collaboration has been established, the researcher from Puget Sound must submit his or her research protocol as a co-investigator to the research collaborator's animal care and use committee or review board. It will then be the responsibility of the researcher and that board to ensure that the procedures for use, care and housing of the animals are followed appropriately.

Any institution with a formal mechanism for reviewing and monitoring the use of non human animals for research purposes can be contacted for potential collaboration. It is the responsibility of the researcher from the University of Puget Sound to locate an institution, to establish a collaborative relationship with an individual or group there and have approval by the collaborator's institution's IACUC before commencing research activity including caring for animals.

Faculty members who use non human animals in their courses for teaching or classroom demonstrations may or may not need to follow the procedures regarding collaboration and IACUC approval depending on the nature of the activity. It is the responsibility of those faculty members to be familiar with the federal, State and local guidelines so as to be aware of activities which may require a formal review process. These faculty members should also be familiar with and abide by the specific policies concerning the use of animals in their particular discipline such as the "Guidelines for Ethical Conduct in the Care and Use of Animals" published by the American Psychological Association.

As of the writing of this document, IACUC approval is not needed for birds, rats of the genus *rattus*, and mice of the genus *mus*. Exempt or not, all institutional use of non human animals must ensure their ethical and sensitive use.

References

U.S. Department of Agriculture. (1991, February 15). Animal welfare; Standards; Final rule. *Federal Register*.

American Psychological Association. (1998?). Guidelines for Ethical Conduct in the Care and Use of Animals.