Attachment D

Institutional Review Board
Report to the Faculty Senate

AY 2010-2011

The Institutional Review Board (IRB) exists for the purpose of protecting the rights, health, and well-being of human beings solicited and volunteering for participation as research subjects. In the context of reviewing proposed research studies involving human subjects the IRB gives very careful attention to issues such as potential risks to participants, protection of participants' identities and disclosed information of a sensitive nature, safety, ethical recruitment practices, and the accessibility and adequacy of informed consent. This is a report to the University of Puget Sound Faculty Senate regarding activities of the IRB during the 2010-2011 academic year.

In the past the Institutional Review Board has met once a month to consider protocols and discuss policy in any time remaining. This year the IRB moved to a schedule of meeting twice a month. The first meeting of each month was devoted to the consideration of protocols and the second was solely for discussion of policy.

I. Charges to the Committee and Our Response

On October 11, 2010, the Faculty Senate approved the following charges to the Institutional Review Board:

1. *Continue to monitor protocols and maintain and monitor records for research involving human subjects.*

This remains the major portion of our work as a standing committee. By the end of the academic year seventeen protocols and two modifications will have been considered by the full Board. At this point, twelve protocols and one modification have been approved, three protocols and one modification are pending review.

Reports of protocols that were classified as exempt or expedited by departmental designates will be appended to an amended version of this report.

2. *Post and monitor current IRB information on the webpage for UPS researchers and work to improve information regarding the IRB submission process for students and faculty advisors of student research. This will include a revision to the documents which are intended to serve as a guide and provide examples for research protocols.*

We certainly spent time in discussion of these issues and have begun to produce drafts of a revision of the handbook. One of the major areas of creative tension in our discussions throughout the year was the fact that the procedures and guidelines followed by the Institutional Review Board were designed at the federal level for regulation of biomedical research but are now being applied to research in the social sciences and humanities. Members of the university community in those disciplines do not always feel well-served by

the rules designed for a very different type of research with different problems and risks to participants. For that reason, in addition to simply re-organizing and rewriting the handbook, we have been considering how to handle the array of types of research protocols that come to us. If you look at the current handbook, you will see that the examples of protocols are all from the biomedical class of protocols. As we revise the handbook we hope to make it much more accessible and usable by students in the social sciences and to give them excellent examples of protocols in their area of research.

As we considered the handbook, we looked at our coversheet and compared it to those of other institutions. We have revised the coversheet to make it look more professional. An example of the proposed coversheet is attached.

3. *Finalize the implementation of a memorandum of understanding with the Office of Institutional Research regarding oversight of OIR work.*

This issue was not considered this year. With a new director of the Office of Institutional Research, perhaps we should reopen this conversation.

4. *Work with the PSC to revise the Research Misconduct Policy.*

During the fall semester we compared the old Scientific Misconduct Policy (old enough to have 756 prefixes for the phone numbers) and the current Faculty Code to bring the Misconduct Policy in line with University policy and rules for grievances. The differences noted and changes suggested were then communicated to the chair of the Professional Standards Committee. A final document has not yet been approved.

5. *Develop and distribute (via the IRB website) a set of procedures for researchers wishing to appeal a decision by the Board regarding a research protocol.*

We did not deal with this issue this year.

6. *Investigate and provide guidance for researchers regarding the responsibilities, legally and ethically, for reporting evidence of child abuse which comes to light in the process of research involving human subjects.*

We discussed this topic briefly at the beginning of the fall semester but have not developed policies in this area.

7. *Draft and implement a Research Integrity Policy.*

Throughout the course of the year, in each of the issues we have discussed we have always considered “best practice” in the conduct of research. For instance, both the National Institutes of Health (NIH) and the National Science Foundation have recently mandated training in research ethics for all persons (faculty, graduate students, and undergraduates) doing research supported by those agencies. We have discussed how to make the campus community aware of this requirement and whether to generalize that requirement to all of us

doing research on campus, whether supported by the NIH or not. In this case, we once again came up against the diversity of research that is done here. Is there some kind of universal training in research ethics that could be made available to the campus community? The NIH offers an on-line course in research ethics, but it is a course that is geared toward those doing research in the biomedical fields. The Collaborative Institutional Training Initiative (CITI) offers research training in a variety of fields including the social and behavioral sciences, but institutional access to those courses requires an institutional subscription.

While we have discussed an array of issues that impinge on research integrity and the conduct of research, we have not yet developed a policy on research integrity.

II. Other Issues Discussed During the Year

A. Research Involving Human Subjects Conducted Outside the United States.

We considered whether protocols for research involving human subjects outside the United States should automatically be required to go through a full IRB review. This discussion came primarily out of concern for students doing research in developing countries where they may be somewhat naïve about the social and political climate of those countries. Students may not understand that asking questions that would be rather routine in the US might put those answering the questions at some risk. For that reason, we looked at how research in foreign countries was handled by Institutional Review Boards at other (largely research) universities. We note that these institutions have a section on the responsibilities of researchers working abroad in their handbook and will include such a section in our revised handbook (for examples, please see the IRB minutes of Oct. 20, 2010). At our most recent meeting, we voted to require any research protocols for human subject research be approved by both the departmental designate and the Chair of the Institutional Review Board. The chair may designate the protocol for a full board review. This will be added to the new coversheet.

B. Evidence of Research Ethics Training

While the Schools of Occupational and Physical Therapy routinely have their students complete the NIH on-line course in research ethics, other departments do not. Institutional Review Boards at other universities require evidence of completion of a course in research ethics as a part of the submission of a protocol. We discussed making this a requirement here. Such a requirement is contingent upon finding courses that are appropriate for the wide range of research projects pursued across the campus.

III. Self-Charges for 2011-2012

At the most recent meeting we discussed the work we would like to see the Institutional Review Board continue and what new business we should address. Our areas of concern include the following:

1. In consultation with the Professional Standards Committee, complete the revision of the Scientific Misconduct Policy.

2. Complete revision of the handbook.

3. Once the handbook is complete, update the IRB website to reflect the changes and make the site easier to navigate.

4. Design and implement a program for training of departmental delegates

5. Continue to discuss the ways in which the IRB can be more transparent and supportive of research on campus. We understand that members of the campus community can see the IRB as a hoop that must be jumped through on the way to research or, much worse, as a group that stifles the academic freedom of scholars. We would like to engage the campus community in a discussion of the role of the IRB on campus, both to help the community understand how we see our role and to seek the input of the community as we finish revision of the handbook. For that reason, we have been in contact with Julie-Neff Lippman to ask to arrange a "Wednesday at Four" discussion on the role of the IRB early in the fall semester, 2011.

6. Finally, we note that the IRB is one of the few standing committees on campus that does not have a student member. While the members of the IRB do not think that having a student as a voting member of the committee would be appropriate when we make decisions about protocols, we do think that having a student member who participated in discussions would help students understand the work done by the IRB and our role in the campus community. We respectfully ask the Faculty Senate to consider adding a student member to the Institutional Review Board.

Respectfully submitted,
Mary Rose Lamb
Institutional Review Board Chair, 2010-2011