Attachment A

Institutional Review Board
Report to the Faculty Senate

AY 2011-2012

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 2011-2012 academic year.

Senate charges for the IRB AY 2011-12:

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

b. Finalize the implementation of a memorandum of understanding with the Office of Institutional Research (OIR) regarding oversight of OIR work.

c. 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.

d. 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.

e. Draft and implement a Research Integrity Policy.

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

g. Complete the revision of the IRB handbook.

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

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

j. Continue to discuss the ways in which the IRB can be more transparent and supportive of research on campus.

The actions taken by the IRB during the 2011-12 academic year in response to each of these charges are as follows:

a. As charged, the IRB engaged in the review and monitoring of research protocols involving human subjects throughout the 2011-12 academic year. In line with the IRB designate structure and consistent with past history of review, the majority of research protocols were reviewed at the departmental IRB designate level due to their characterization by the appropriate designate as qualifying for 'exempt' or 'expedited' status – meaning that the study procedures, level of risk, sampling methods, or nature of participant population did not fit the criteria established by federal and university standards for full Board review. One additional element of review which follows from a policy change in 2010-11 involves a requirement that a full member of the standing IRB committee, most often the Chair, review protocols, regardless of their standing, which involve research abroad prior to final approval.

Ten protocols were reviewed by the full Board and of those six were approved. Two were deemed appropriate for designate-level review and returned to the appropriate designate. Two have been granted approval contingent upon minor revisions not yet received by the Board. In this academic year, a total of x protocols were classified as 'exempt' (8 so far, but there will certainly be more in my final draft of this report. see below.) and y were approved by an IRB departmental designate under the 'expedited' classification.(16 so far but to be updated.) In addition, the IRB Chair reviewed and approved four protocols classified as expedited that involved research outside of the United States. (I have not yet received a response to my request from CSOC, Psychology, Exercise Science, and Occupational Therapy for year end designate reports.)

b. The Board did not take up this issue this year. Although Associate Dean Ferrari facilitated an initial contact between the recently hired director of Institutional Research and the IRB Chair, neither of us followed up on this.

c. The Board did not take up this issue this year.

d. The Board did not take up this issue this year.

e. The Board did not take up this issue this year.

f. The Board forwarded recommendations regarding revisions to the scientific misconduct policy to the Professional Standards Committee (PSC). In addition, the Chair and Associate Dean Ferrari met by request with the PSC to provide further clarification regarding the issues of reconciling the misconduct policy and the faculty code.

g. The Board took initial steps to identify areas for improvement in the Handbook, but no revisions were implemented to date. A modified cover sheet for research protocols has been completed and will be posted on the IRB website.

h. The Board identified an immediate need and opportunity to improve the experience of researchers and departmental designates by updating portions of the Board website to improve the information and user friendliness. We expect that these changes will be implemented before the beginning of the new academic year.

i. The Board made plans to initiate an outreach program to small groups of designates once the changes to the IRB website are implemented. The purpose of this will be to provide both training and solicit feedback regarding the changes.

j. This was a frequent issue of discussion on the IRB this year. There was substantial discussion of recently proposed changes to federal guidelines relating to human subjects research and their impact on our approach. Discipline-specific changes to the IRB review process were further discussed but the Board has tabled these issues pending the outcome of the proposals for change at the federal level.

Self-charges for the IRB AY 2011-12:

The Board presents the Senate with the following self-charges for AY 2011-12.

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

2. Continue progress on revisions to the IRB website, including a revision of the handbook documents.

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

4. Monitor changes at the federal level regarding regulations and requirements related to human subjects research.

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.

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.

Respectfully Submitted,
Garrett Milam, PhD
IRB Chair AY 2011-12

Attachments (5): Designate reports for Physical Therapy, School of Business and Leadership, Office of the Associate Deans, and Politics and Government, and Economics.