

Institutional Review Board
Report to the Faculty Senate
AY 2014-2015

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 2014-2015 academic year.

2014-15 IRB membership: Tim Beyer (co-chair F'14), Kirsten Wilbur (co-chair F'14/chair Sp15); Lisa Ferrari (ex-officio), Joel Elliott, Renee Houston, Jung Kim, Mita Mahato, Siddharth Ramakrishnan, Brad Richards, Justin Tiehen, and Troy Christensen (community representative).

This academic year the Institutional Review Board reviewed 103 proposals. Of these 10 were full board (7 approved, 3 pending), 87 were expedited (76 approved, 11 pending), and 6 were exempt (6 approved). In addition the board focused on completing the formal Senate charges as addressed below.

2014/2015 Senate charges to the IRB and IRB response:

- 1. Streamline the existing University of Puget Sound IRB protocol process where possible and communicate with IRB-reliant departments regarding revision of the post-designate IRB protocol process.**

This past year we had a board of seven faculty members and one community member. The IRB protocol process, now that we do not have the departmental designates is to have all IRB protocol submissions go through Jimmy McMichael in the Associate Dean's office. Mr. McMichael then sends all expedited and exempt protocols out to committee members on a rotating basis. All full board protocol submissions go out to all board members for discussion at the next scheduled IRB meeting. Tim Beyer and I have meet with the representatives of the History and Sociology and Anthropology departments this past fall semester to discuss how to handle Oral Histories. Additionally, the departments of Psychology, Communications, Exercise Science, Occupational Therapy, and Physical Therapy have been instructed on the new procedures in place for submitting and reviewing of protocol proposals. All protocol submissions, approval documents and email communication are now stored on the irb share drive.

As a way to further improve the approval process I would recommend the IRB board continue to discuss how best to communicate and track proposal submissions which need further modifications, changes and/or additions.

2. Finalize and conclude revisions to the IRB handbook and the website.

Revisions to the IRB handbook were finalized at our October meeting and the IRB handbook was posted to the IRB website. The revisions include changes to the IRB protocol proposal process as well as changes to the IRB protocol cover sheet. In addition the board tried to simplify the process for determining if a study requires full board, expedited, or exempt review. Many of the proposed changes were submitted to the Senate with last year's year-end report.

Work has been ongoing with changes to the IRB website. Dr. Siddharth Ramakrishnan has taken the lead on working with Barbara Weist in the Communications office and the board should be ready to unveil the new website at the conclusion of spring semester this year. Students and faculty should find it easier to gain access to the IRB webpage and it has been formatted to lead the viewer to the forms needed for an IRB submission by providing link embedded in the text. Additionally, when the CITI training modules become agreed upon there will be links on the IRB webpage for student, faculty, and IRB members to access the CITI training modules.

3. Finalize CITI training procedures and disseminate information regarding CITI training to faculty and departments.

This past semester the IRB was introduced to the CITI training by Lisa Ferrari and all members spent time completing the various modules to decide which modules would be best suited for student training, faculty training and IRB member training. At our December board meeting it was decided that students could undergo minimal training and that perhaps the training could be embedded within the research methods course the student is part of. Students would need to complete *Students in Research* and *Avoiding Group Harm* modules and submit a completion certificate with their protocol submission. The date of the certificate needs to be within four years of completing the training. It was decided that additional modules are available as needed or recommended by the project chair.

All campus faculty members would have access to the training on a yearly basis and it is recommended they complete the *Belmont Report* and *Defining Research with Human Subjects* modules. For faculty who chair a student project the faculty member would only need to take the training every three years and not need to repeat for every student.

For an IRB member new to the board they would be required to take the *New IRB Member* module and all IRB members would complete the following modules: History and ethical principles, *Federal Regulations*, *Assessing Risk*, and *Informed Consent*. In addition, the chair of the IRB would be required to complete the *Unanticipated Problems* module.

The board decided that modules can be added as needed. Currently the board is waiting to link the CITI training on the revised IRB webpage pending approval from the CITI training organization.

4. Explore options for significantly reconfiguring the IRB protocol process options, based on the experience of the Puget Sound IRB and the experiences of similar small, private liberal arts colleges.

IRB members have met with representatives from the departments of Psychology, Sociology and Anthropology, and History to discuss such topics as what constitutes a research project and what is a class project and how do oral histories fit with the IRB process. We have established an MOU with the Psychology department and an MOU with the department of Sociology and Anthropology is in the draft stage.

The board has attempted to simplify the IRB protocol process by revising the IRB webpage and offering links to the various IRB forms and text explaining how to determine if a project requires full board, expedited or exempt review. In addition, the IRB handbook has been revised to provide a clear understanding of the IRB process and examples of documents such as the different consent forms that might be needed in addition to an “investigator’s checklist.” These forms will also be able to be accessed from the IRB webpage.

After a review of the IRB process at universities similar in size to Puget Sound the board has determined that oral histories as such do not meet the federal definition of “research” in the sense of contributing to generalizable knowledge, however the University of Puget Sound IRB will require projects to be submitted for exempt status review. In situations where the population or area of inquiry will directly result in substantial risk to participants the project will be submitted for expedited review.

5. With respect to the work of the committee during 2014-15, indicate in your end of year report whether the size of the committee was appropriate and identify any committee work that seemed superfluous.

The size of the board was the same as last year and there was an increase in the number of IRB protocol proposals by eight additional proposals. One of the full board reviews this year from an outside agency was complex and required two meetings for discussion. Each member read between 10 and 15 proposals this year, including the full board reviews. Several of the IRB members did not continue into the spring semester due to sabbaticals; however the board recognizes the difficulty of increasing the membership and trying to find a common time for monthly meetings.

My experience as a co-chair in the fall semester with Tim Beyer was beneficial in sharing the load of the chair and I found that my time spent on IRB matters increased significantly in the

spring semester while Dr. Beyer was on sabbatical. I would recommend the position of chair be co-lead in the future.

Respectfully Submitted,

Kirsten Wilbur, MSOT, OTR/L
IRB Chair AY 2014-15