

Minutes
Institutional Review Board
September 5, 2012

Present: Garrett Milam (Chair), Lisa Ferrari, Anne James, Andrew Rife, Grace Faucett (Grad Student Rep), Kirsten Wilbur, Eda Gurel-Atay, Mita Mahato, Ross Singleton (Senate Liaison).

Meeting was called to order at 3:00pm.

Orders of Business:

1. **Senate Liaison.** Ross Singleton, IRB liaison from the Faculty Senate, began the meeting. His role is to keep abreast of the IRB committee work and keep the Senate informed, particularly re: changes in policies or procedures that may impact the University community. He will communicate directly with the IRB Chair and come to meetings, as needed. The Senate charges to standing committees will be out by the end of September. Charges to committees are often derived from End of Year Reports. Garrett Milam (IRB Chair 2011-2012) will distribute the report to all current IRB members so all have the document.
2. **Nomination and Approval of IRB Chair for 2012-2013.** Singleton also facilitated the nomination and selection of chair. Milam was nominated and received unanimous approval from IRB members.
3. **Permanent IRB Meeting Time.** IRB members agreed that the initial meeting time (Wed, 3:00 – 4:00pm) was convenient for all and will be the time for Fall 2012. Meetings will take place in Wyatt 226. As in past years, the IRB will meet every-other week. Meetings will alternate between administrative work and protocol reviews. Milam will email a meeting schedule to IRB members to confirm dates and type of meeting. Only protocol meetings will be posted on the IRB website.
4. **Update on National Standards and Standards of Compliance.** Lisa Ferrari attended a conference at Washington University this summer re: National IRB Standards and Standards of Compliance. She gave a brief summary of information that will shape the administrative work of the IRB over the coming year, including:
 - Researchers have more flexibility in the consent process than the Puget Sound IRB has been requiring, which might address some of the concerns raised last year re: research that poses minimal risk and where written consent may interfere with the study, e.g., ethnographic field research.
 - Not all studies involving children require full-board review. Some meet criteria for expedited studies and can be reviewed by one board member.
 - The biggest issue is that the Department Designate system that the Puget Sound IRB has relied on for review of exempt and expedited studies is out of compliance and will need to be revised. Full IRB members are the only people who can review proposals, *including* exempt and expedited proposals. Exempt and expedited reviews may be conducted by *one* person, however that person must be a full IRB member, and the Designates do not meet that criterion. This announcement led to considerable discussion. Points to consider as the IRB reviews and revises procedures to meet standards includes:

- This will greatly increase the work of the IRB. It was estimated that there were close to 100 IRB proposals handled by Designates last year that would need to be reviewed by the IRB members. Some departments may require IRB proposals for class-based assignments that do not meet the Federal definition of research, but do meet course objectives. Departments may need to continue to handle these on the Departmental level.
- Andrew Rife commented that the Designates have provided a useful link in answering questions regarding proposals that underwent full IRB review and wondered if losing the Designates would have a negative impact on the IRB's ability to review research out of the expertise of Board members. Milam responded that the researchers are able to attend the IRB meeting and should be able to answer these kinds of questions.
- Anne James asked if we could keep the Designate system, particularly for student projects, to help increase the quality and clarity of proposals submitted to the IRB. Ferrari raised concern re: using faculty in this way (given other demands on their time) and that it might slow the overall process for researchers. Milam suggested that we might place the onus on faculty advisors of student projects to disperse the burden over more people.
- Rife recalled that someone at the Wednesday @ 4 that focused on the Human Subjects Review process, raised a concern that they, as designate, might have liability or responsibility. Ferrari stated that was a legitimate concern as technically the Designate is not an IRB member.
- Milam asked about the time frame for revising the Designate system. Ferrari reported she had talked to Kris Bartanen about the problem and the goal is to correct the problem by AY2013-14. Milam suggested in the meantime, we might want to ask Designates to kick specific types of expedited studies to the full IRB, e.g., where there are questions about consent, vulnerable populations, or foreign studies. Rife suggested that we consider a transition plan so that the procedures are in place by the end of this academic year. This would also demonstrate a good-faith effort to correct the problem.
- Eda Gurel-Atay asked if it is possible for the IRB to have part-time members that would expand the number of faculty on the full IRB. Ferrari suggested it would be an option for some members to only participate in protocol meetings.
- James asked if we want to invite representatives from departments that submit many protocols, e.g., Psychology, to have input into the revision of the process. Most other departments that regularly submit research proposals currently have representation on the IRB (e.g., Andrew Gardener can represent Comparative Sociology, James and Kirsten Wilbur can cover OT and get input from PT colleagues, and Gurel-Atay can represent Business & Leadership).
- Milam will set an agenda for how to move forward.

The meeting was adjourned at 3:50pm.

Respectfully submitted,

Anne James