Minutes
Institutional Review Board
October 10, 2011

Present: Garrett Milam (Chair), Lisa Ferrari, Andrew Gardner, Anne James, Mary Rose Lamb, Julia Looper, David Lupher, Andrew Rife, Yvonne Swinth
Meeting was called to order at 1:00 pm

Announcements: None

Orders of Business:

1. **Reviewed proposed modifications and request for renewal of Proposal 0910-12.**
   Modifications were in response to an error discovered in the proposal by the researchers. Renewal was requested for additional time for data analysis.
   ACTION: Unanimous approval of modification and renewal.

2. **Discussion of upcoming "Wednesday at 4" presentation/discussion of "IRB, Human Subjects, and Academic Freedom."**
   - Discussion ensued re: the following:
     - Gardner stated he is willing to take the lead on Wednesday, but expressed concern that it may be difficult for him to accurately reflect some of the intricacies of IRB process and requirements and wondered if the agenda, as outlined in his email, was too focused on his disciplinary perspective.
     - Looper stated that a brief overview of the history and procedures might help focus the discussion, being careful not to make it presentation focused on the IRB process.
     - There was discussion re: how varied IRBs interpret guidelines differently, which can be frustration to researchers collaborating with colleagues in other settings.
     - The challenges of evaluating IRB applications for research to be conducted abroad was raised, including IRB members being unfamiliar with social norms, cultures, and/or governmental regulations in other countries that might influence treatment of human subjects.
     - The members of the IRB also discussed some of the vagaries inherent in exceptions to requiring written informed consent, which can present problems, particularly in non-medical research for foreign or disenfranchised populations.

   ACTION: Since the Wed at 4 session is limited to 1 hour, the group decided on the following:
     - **Gardener will introduce participating members of the IRB and "set the stage" for a productive discussion focused on how the IRB can: 1) Make procedures as structured and relevant as possible for Puget Sound researchers, and 2) Provide the university community with the resources they need so the IRB can make a fully-informed decision based on the IRB application. There will be a flip chart available to record suggestions.**
     - **Looper will begin the session with a brief history of the IRB and brief overview of the designate system used at Puget Sound.**
     - **James will briefly describe the definition of research and the levels of review, including that exempt and expedited studies do not go to the full IRB.**

- **Other content discussed above will be addressed as it comes up from participants to ensure the session addresses their concerns.**

- Additional issues that arose during discussion that were tabled for future consideration included:
  - Need for training for new IRB members and for IRB department designates.
  - Possible training in protection of human subjects for all researchers (now currently required for researchers receiving federal funding).
  - Adding links to the UPS IRB website to the government information on human subjects and IRB, in particular, the flow chart that can be very helpful in determining what constitutes research, criteria for the three review levels, and decision-making around the need for written informed consent.

3. **Conclusion of discussion re: reconciling the Research Misconduct Policy with the Grievance Policy in the Faculty Code.** (see notes for initial discussion in 9-26-11 IRB Meeting Minutes).
   - At the end of the prior meeting, the IRB had recommended:
     - Allegations of research misconduct should follow the process layed out in the University's Research Misconduct Policy through its conclusion.
       - Penalities assigned to faculty, staff, and/or students must be relative to the research misconduct.
     - In situations where the research misconduct included a violation of other University standards (e.g., violations of academic integrity for students or profesisonal ethics for faculty) that warrent consideration beyond the Research Misconduct Policy, additional action may be initiated through the appropriate adjudicating bodies, as follows:
       - Academic Standards Committe for students
       - Grievance Procedure outlined in the Faculty Code for faculty
       - Human Resources department for staff
   - This recommendation, however, creates a conflict with the timeline outlined in the Grievance Procedure of the Faculty Code, which states that a grievance must be put forth within 30 days of the alleged violation or the discovery of the alleged violation. The Professional Standards Committee may wish to consider a revision that reflects a timeline extension for grievances related to research misconduct, allowing the grievant 30 days after conclusion of the research misconduct process.
     - It is the view of the IRB that this is likely the simplest way to reconcile the two policies as many of the research misconduct policies and procedures are dictated by federal regulations.

   ACTION: Milam moved that the IRB make the above recommendations to the Chair of the Professional Standards Committe, who requested IRB input on this issue.
     - **There was unanimous approval of the recommendations.**

The meeting was adjourned at 1:55pm.

Respectfully submitted,

Anne James