

## **Institutional Review Board**

**May 8, 2008**

Draft 2

Present: Roger Allen, Jim Evans, Lisa Ferrari, Marsha Gallacher, Tatiana Kaminsky, Garrett Milam, David Moore, Ray Preiss, Ann Wilson

Visitor: Jimmy McMichael, Office of the Associate Deans

The meeting was called to order at 1:00 p.m.

Roger Allen reported that there were no protocols to review.

**Report to Faculty Senate:** Roger Allen distributed the IRB report that he presented to the Faculty Senate. As part of the reporting process, he identified three self-charges for the IRB for AY 2008-2009 that were shared with the Senate. Those charges are to:

- continue to review protocols.
- explore the feasibility of the IRB becoming registered/certified by Federalwide Assurance, which is an agency under the umbrella of the Office of Human Research Protection in the Department of Health and Human Services.
- monitor and update the IRB web page on the UPS website.

**Subcommittees for AY 2008-2009:** Given the amount of IRB time devoted to reviewing protocols, it is often difficult to take care of other issues related to the functioning of the IRB. With that in mind, the board agreed to form a number of subcommittees next year to address important issues and to inform discussion among the full board. Three topics were identified as issues that various subcommittees could reasonably consider:

- revising/updating and maintenance of the IRB web page
- working with Department Designates regarding their role, criteria for reviewing exempt and expedited protocols and a centralized reporting system regarding the status of reviewed protocols
- exploring the details and feasibility of becoming affiliated with the Federalwide Assurance program

**IRB Web page:** Lisa Ferrari noted that the introductory comments on the IRB web page may not accurately reflect the scope of the IRB and that it is often difficult for individuals looking at the page to find information at a glance. She drafted some ideas for changes in format and language that might make the information more easily retrievable which were shared with board members. Other ideas that were discussed included adding a section that helps researchers understand which types of activities require IRB review and which do not, the addition of FAQ's related to the purpose of the IRB and links to relevant documents such as the NIH website and the university's bloodborne pathogens policy. While several changes were made to the Guidelines document at the end of AY 2006-2007, some of those changes have not yet been reflected on the web page. A question was also raised as to whether or not the IRB needs to have a designated ombudsperson and whether it would be useful to have contact links for department designates and the IRB chair (possibly having a dedicated email address such as [irb@ups.edu](mailto:irb@ups.edu)). These are all issues that the webpage subcommittee can use to frame its work when it is formed in the fall.

**IRB Registration with Federalwide Assurance:** Roger Allen brought up the issue of having the IRB explore the possibility of becoming registered with the Federalwide Assurance program through the Office of Human Research Protection (OHRP). Lisa Ferrari shared some information that she had regarding the process. It appears that this registration would be similar in some

respects to other programs within the OHRP, one of which the IRB is already registered with, and would meet the requirement for IRB oversight that researchers who were applying for federal grant funding often need. The process of investigating this further will be a charge of one of the subcommittees that will be formed in the fall.

**Follow-up Forms on Project Status:** The IRB reviewed three project status forms, all of which had completed during the 2006-2007 AY. There were no self-reports of any unusual circumstances from any of these studies.

**Electronic submissions of IRB protocols:** The issue of being able to submit IRB protocols electronically as well as establishing an online version of the project status follow-up form was brought up briefly and then tabled until next fall. Exploring the possibility of electronic protocol submissions and reporting will be an additional self-charge of the IRB for AY 2008-2009.

**Thank you:** Roger Allen reported that he had explained the significant contribution that Marsha Gallacher has made as the community member of the IRB to the Faculty Senate when he made the year-end report. The board affirmed this at the meeting and formally acknowledged Marsha's contributions as well.

The meeting was adjourned at 1:55 p.m.

Respectfully submitted,

Ann Wilson