Institutional Review Board
November 9, 2007

Present: Roger Allen, Jim Evans, Marsha Gallacher, Tatiana Kaminsky, Sally McCoy, Garrett Milam, David Moore, Sarah Moore, Karim Ochosi, Ray Preiss, Ann Wilson,
Visitor: Jimmy McMichael, Office of Associate Deans

Introduction: Roger Allen introduced Jimmy McMichael, Records and Computing Specialist in the Office of the Associate Deans. Jimmy's role on the IRB is to maintain records, send protocols to IRB members for review and update and maintain the IRB page on the UPS website.

Question from BLP: Sally McCoy reported that a faculty member from the Business Leadership Program contacted her with a question regarding the need to have IRB oversight for a description of a class project that was submitted for publication. While the class project involved taped interviews, the description of the project did not include any information from those interviews. The Board decided that such a project was not one that required IRB approval and oversight and suggested that McCoy refer the faculty member to the Office for Human Research Protection website which clearly differentiates between educational projects of the nature described from research investigations in which human subjects are involved.

Protocol Review:

#0708-003 Board members questioned the reason that this protocol required full board review since the materials submitted appear to meet the criteria for an exempt review by the department designate. The board suggested that the department designate (who was present at the meeting) request that the researcher provide a letter from the school district in which the study will be conducted verifying its agreement to allow the study to take place. The board also suggested a few minor revisions to the surveys which were passed along to the department designate
ACTION: The board voted (11-0) to send the protocol back to the department designate for review and approval pending receipt of the letter of agreement described above.

Guidelines for Review of Protocol Revisions or Modifications: Allen described a situation which had arisen recently in which a researcher with a protocol previously approved by the full board wished to make minor modifications to the protocol which do not substantively change either the intent of the study or the level of risk to the participants. The current policy regarding the way in which modifications are handled and the timeline for submitting modifications is vague. After discussing this issue, the board decided that the IRB chair (or the Associate Dean if the modifications are requested during a break or in the summer) will review the request for modifications. If the modifications do not significantly change the original intent of the study or alter the level of risk to the participants, the chair or the Associate Dean can respond to the researcher without input from the rest of the board. If the chair or the Associate Dean decided that further review is necessary, the modifications request will be referred on to the full board. The timeline for reporting back to researchers who request modifications which can be handled by either the IRB chair or the Associate Dean will be within 10 working days of receipt. The language regarding these procedures will be added to the IRB Guidelines Document on the web site.

Registration with Office for Human Research Protection: Allen reported that Institutional Review Boards can be registered with organizations which is sometimes required if research is federally funded. He asked whether the IRB at UPS should seek to become registered with the Office for Human Research Protection (OHRP). The purpose of this registration is to assure that our procedures for assessing protocols meet the standard set by this organization. McCoy indicated that federally funded research often requires that the IRB with oversight of a particular study provide the OHRP registration number. Allen indicated that the registration process involves gathering information as to the constellation of the board and administrators at the university, providing a description of the protocol review process and the process for handling complaints. The registration requires ongoing maintenance in that it must be updated annually as board members change and to reflect changes in procedures.

Sarah Moore indicated that the UPS IRB is already registered with the Office of Research Integrity (ORI) which requires a yearly report on the number of complaints received and how those complaints are resolved.

The board discussed the pros and cons of the registration process including the need to update the information annually balanced with the notion that by registering we would gain a deeper understanding of how our board compares to others procedurally and otherwise. The issue of cost for registration was raised. Allen indicated that he would look into the costs associated with registration.

ACTION: The board voted (11-0) to seek registration with the OHRP.

Discussion/Approval of Website Changes: Allen asked board members if there were any additional substantive changes that needed to be made to the Guidelines Document before it is put on the IRB page of the UPS website. A few members indicated that they had very minor editorial changes. Allen suggested that the editorial changes be sent to him in hard copy form. He will incorporate the changes into the document and forward it to Jimmy McMichael for formatting and adding to the web page. Allen indicated that he would add the information regarding the handling of modification requests to the revisions.

ACTION: The board voted (11-0) to approve the changes in the Guidelines document with the minor editorial changes that members are submitted and to post the revised document on the IRB web page as soon as it is ready.

The meeting was adjourned at 11:55 a.m.

Respectfully submitted,

Ann Wilson