Institutional Review Board Minutes March 1, 2007

Members present: Allen, Evans, Gallacher, Kaminsky, McCoy, Ochosi, Wilson

The meeting was opened at 11:02 AM in Wyatt 326

- 1. Update on Protocol #0607-011
  - The student researcher is revising the protocol and will be working with McCoy to address the issues brought up by the Board in the February 8<sup>th</sup> meeting. We will see the revised protocol in the April IRB meeting. The student researcher and the faculty advisor will plan on attending that meeting.
- 2. A question was raised about a survey that is being conducted by the College Board, which administers the SATs and AP exams.
  - This off-site group is planning on surveying college applicants and would like to include applicants to UPS. The question before the Board was whether or not we needed to review the study and study materials before the survey was given to applicants.
  - The researchers submitted examples of questionnaires that have been used for previous studies. The sample survey that was submitted was long. One part had 36 items and the other had 126 items. The researchers also indicated that they would be looking at applicants' GPA and SAT scores.
  - Given that the protocol that was submitted was not for the study that would be conducted with UPS students, it was difficult to assess the risk for the proposed study.
  - There was some concern about conducting research with a vulnerable population (some applicants will likely be minors), especially given that the survey asks potentially sensitive questions.
  - The Board felt that we do need to see the protocol of the current study. In addition, if the researchers have gone through IRB review at another institution, we will need to receive information about that as well.
- 3. Training workshop for department designees
  - We need to follow up with departments to find out who the designee of each department is. If there is no designee named, the chair acts in that role.
  - Wilson has agreed to run a training workshop for designees. The workshop will be sometime in April.
  - McCoy will send letter of invitation to the designees to attend.
  - There was some discussion about creating a checklist for expedited reviews to assist designees in making sure all information is included in the protocol and consent form.
- 4. Reviewing the IRB guidelines.
  - Wilson and Gallacher have started working on reviewing Sections 4 and 6 in the IRB guidelines.
  - The following issues were discussed for section 4:

- The HIPAA statement is now included. There was some discussion about whether or not the confidentiality statement needed to be included if the HIPAA statement was used. The Board decided that the HIPAA statement was sufficient.
- There is a statement in the guidelines about adherence to the blood borne pathogen policy if handle bodily fluids. Do we need to have the policy as an appendix in the guidelines or as a link? After some discussion, the Board decided to have a link with a statement that is signed saying that the researchers have read and are familiar with the blood borne pathogen policy.
- Discussion about making sure that the protocol guidelines and the checklist (Appendix 1) have the same language.
- The following issues were discussed for section 6, which deals with the consent form.
  - Wilson and Gallacher have been working on clarifying language and level of detail.
  - $\circ~$  We need to have 1.25" at the top of the form for the stamp. A template will be created.
  - Discussion about how the consent form will be stamped for expedited reviews. The Board decided that the consent forms will need to go to Jimmy McMichael for the stamp. An approval letter and the consent will need to come directly from the department designee so that Jimmy knows which forms are approved.
- Discussion about sample consent forms and what should be included. The following were discussed as important: adults, children, HIPAA, qualitative study, videotaped or audiotaped data, minimal risk, more elevated risk, cognitive disorders (where another party will sign the informed consent form for the participant), studies involving deception. We also want to make sure a variety of departments are represented, including OT, PT, exercise science, psychology, sociology, religious studies, etc. Evans and McCoy will try to get examples, but examples from the past will need to be formatted to match new guidelines.
- Review of guidelines will be continued.

The meeting was adjourned at 11:55 PM.

Respectfully submitted, Tatiana Kaminsky, IRB Secretary