Institutional Review Board Minutes
February 8, 2007

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

The meeting was opened at 11:03 AM in Wyatt 326

1. Update on protocol that was reviewed in the fall.
   - #0607-006 has been abandoned

2. Meeting dates for spring semester have been set for the first Thursday of the month from 11:00 to 12:00 in Wyatt 326 beginning on March 1, 2007.

3. Question was raised about a study that was done last year looking at the use of a measurement scale with typically developing infants. The author of the scale wants the data to help with developing norms. The data will be anonymous. Can they be shared? The Board looked at the consent form that was used in the study originally. The consent indicates that data will be used to assess the scale, so the Board decided that sharing the anonymous data would be acceptable and gave approval.

4. Reviewing the IRB guidelines.
   - McCoy has broken up the IRB guidelines into sections. Members were given an opportunity to choose the section they would like to review. Those members who did not choose a section will be assigned a section to review.

5. Review of Protocol #0607-010
   - This protocol was reviewed in the January 18, 2007 meeting and was sent back to the student researcher and advisor for revision.
   - There were a few small issues that were still outstanding:
     - Recommend telling participants roughly when the second interview will occur.
     - On the consent form the student researcher cannot use the listed abbreviation behind her name as she has not yet earned her degree. A phone number needs to be listed in the contact information section of the consent form.
     - Discussion about the support the student researcher is being given related to phenomenological research and methods. The Board recognizes that the student's committee members have experience in this type of research method.
     - Typo noted on the sheet that will be sent to clinics. "regards" should be changed to "regard."
   - The Board unanimously approved the protocol pending these changes.

6. Review of Protocol #0607-011
   - This protocol was reviewed in the December 7, 2006 meeting and was sent back to the student researcher and advisor for revision.
   - The following issues were discussed:

- Question about consent and safeguards that will be in place to obtain truly informed and voluntary content to participate in the study.
- No consent form was included with the protocol. How will the student researcher guarantee that consent is informed and freely given?
- Some question about the usefulness of information vs. risk – the Board wondered if the questionnaire was going to be able to provide information that would answer the research question. Benefits at this time do not seem to outweigh the risks and need to be fully thought out. The researcher needs to be more specific about risks and benefits in the proposal. Hypotheses would be helpful here.
- The data analysis plan is general – the Board would like more information about the plan.
- The Board recommends that the researchers attend the next meeting when the protocol is reviewed to help address some of these questions.

- These recommendations will be sent to the student researcher and advisor. The Board will review the protocol again when it is revised.

7. Review of Protocol #0607-015
   - The questions raised by the Board centered around the consent form. Namely the consent form needs to be modified in the following ways:
     - The HIPAA statement needs to be included
     - The condition being studied needs to be defined in a way that the participant can understand
     - The reading level needs to be double checked. It seems too complex.
     - The language in the consent form changes from "we" to "I" – this should be consistent throughout.
     - Include more information about the initial interview being part of the screening process, with the participant not necessarily continuing in the study.
     - The title should be simplified and be more representative about the study. (There was some general discussion at this point about the complexity of many of the titles used for studies. This will be considered further when the IRB guidelines are reviewed.)
     - Under description, change "paper/pencil" to "written"
     - Under costs and payments, change "may be" to "will"
     - Information needs to be added to benefits discussing the benefits of this study for the field
     - Consent form needs to be on letterhead.
   - The Board unanimously agreed to approve the study when these changes have been made. The IRB Chair will review the revised consent form to make sure all changes have been addressed.

8. Review of Protocol #0607-016
   - This is an international, multi-site study. All area coordinators need to go through their own IRBs.
   - The following topics were discussed:
     - The consent form is very long. Can details about the study go in back of the consent form? Can it be a separate schedule of testing? There was some

discussion about how to give the participants the information and still have the consent be informed and not too overwhelming.
    - Add in the protocol that the details of the study will be discussed with parents at the time of consent.
    - When will gift card and toy be given? Will participants receive these even if they withdraw from the study early? Consent form needs to be changed to reflect this.
- The Board unanimously agreed to approve the study when these changes have been made. The IRB Secretary will review the revised consent form and protocol to make sure all changes have been addressed.

The meeting was adjourned at 12:00 PM.

Respectfully submitted,
Tatiana Kaminsky, IRB Secretary