Institutional Review Board Minutes
November 10,2003

Members present: Allen, Cohen, Finney, Foster, Goodman, Preiss, Swinth

The meeting was opened at 11:06 AM in Collins Memorial Library.

1) Review of Protocol #0304-003

The following issues were raised by members of the Board:

- The protocol requires a title.
- The protocol contains two different purpose statements. It should be clarified what purpose the study intends to address via the investigative protocol.
- There is a vast knowledge base related to the population and issues this study intends to investigate. The complete absence of any references to existing work or findings seems to indicate that the student investigator may benefit from learning about the current state of knowledge related to serving this population. Yvonne Swinth, Board member and occupational therapy faculty member, volunteered to meet with the investigator to discuss a direction for obtaining the fundamental background information necessary to conduct a study in this area.
- The consent form requires significant revision, which includes the addition of an "Informed Assent" form for parents to sign on behalf of the child participating.
- No information was provided on the nature or content of questions to be asked participants. An interview script is suggested. The investigator has provided no information on what subject response data is to be collected and should do so in the revision.

Due to the absence of detail specifying what subjects will be asked, the need for extensive consent form modification, and general lack of specificity articulated in the protocol the Board felt the protocol was not yet ready for a vote. The investigators need to complete design of the investigative protocol and articulate it in a revision. A representative of the Board will be discussing the required level of detail and revisions with the investigation's faculty advisor prior to resubmission.

2) Review of Protocol #0304-004

The following issues were raised by members of the Board:

- The protocol presents multiple conflicting purpose statements in different places in the document. The investigator needs to define the precise purpose of this study and develop a data collection strategy and analysis to address that purpose.
- It is not specified what the investigator intends to ask subjects. Either an interview script, or less rigidly structured interview guide is suggested and should be provided in the revision.
- No method of data analysis is described.
- Will demographic data of any kind be collected and if so, what?
- Clarify who the subjects are from the multiple categories described and provide an accurate estimate of the total number of subjects the investigators intend to work with.
- In the consent form, further information must be provided to the subjects regarding protection of confidentiality.
- The consent form language should be consistent with the study.
- In order to truly provide subjects with the information needed to solicit their informed consent, much more specificity is needed in the consent form on description of the procedure, time commitment, participant's rights, etc.

Due to the absence of a consistently expressed purpose or detail specifying what data will be collected and what subjects will be exposed to the Board felt the protocol was not yet ready for a vote. The investigators need to identify a purpose, complete design of the investigative protocol and articulate it in a revision. A representative of the Board will be discussing the required level of detail and revisions with the investigation's faculty advisor prior to resubmission.

The Board felt that neither of the two protocols reviewed were ready to begin data collection. Aside from necessary revisions to consent forms, it appears the student investigators have not yet thought out exactly what the purposes of the studies are, what data will be collected, and specifically how they will obtain that data from participants. Protocols presented for IRB consideration need to have a clear statement of purpose, demonstrate sufficient scientific merit to warrant engaging volunteer subjects, and clearly state exactly what each subject will be exposed to. Prior to submitting an IRB protocol, investigators must work out all the details of their investigative procedures and then articulate those in the IRB document, so that the Board can assess the potential risks and benefits of the study with full knowledge as to exactly what the study intends to investigate and precisely what each subject will be exposed to and asked to do.

3) The next meeting of the Board was scheduled for Monday, December 8, 2003, at 11:00 AM.

4) Meeting was adjourned at 12:01 PM.

Respectfully submitted,
Roger Allen, IRB Secretary