

Minutes
Institutional Review Board
November 28, 2012

Present: Grace Faucett (Grad Student Rep), Lisa Ferrari, Andrew Gardner, Eda Gurel-Atay, Katie Hall (Undergrad Rep), Anne James, Mita Mahato, Garrett Milam, Andrew Rife(Community Rep.), Kirsten Wilbur

Meeting was called to order at 3:03pm by Garrett Milam

Motion to Approve Minutes: Motion was made. Minutes from 14 November 2012 were approved.

Review of Protocol #1213-005

Concerns were raised in the following areas:

- *Recruitment*
 - Milam noted that it is not clear what age of children will be or what teacher/classrooms would be included.
- *Lack of support for study*
 - Gurel-Atay noted that the students should have a letter of approval from the principal of the school and the school district.
 - Need letter of support from Dr. Swinth the chair of the study.
- *Informed consent and protecting confidentiality*
 - Gardner suggested that the informed consent form on page 4 needs to clarify how participants will be given the opportunity to ask questions.
 - Consent forms need to make clear the consequences for not participating in the study.
 - James suggested including in the parent consent form that the child may improve by being a part of the study.
 - Need to clarify what is meant by “healthcare information” and how it will be collected.
 - Recommend removing the request for medical records being used.
 - Gurel-Atay suggested that onn page 2 of the parent’s informed consent recommend removing that the parent may withdraw their approval to use and share the child’s study results by contacting the Principal Investigators in writing and instead mention use of email.
 - James questioned whether the informed consent form for the parent/guardian is actually written at an 8th grade level.
 - Ferrari stated that the Child’s Assent form does not appear appropriate for age 6 and also cannot assume that one document will be sufficient for the age group of 6 to 12 years of age.
 - Hall stated that the consent form needs consistent language.
 - Gurel-Atay suggested that in Appendix C the teacher’s form needs to omit “parent and child” language.
 - Mahato stated that in Appendix E the 4th box was cut off.
 - Mahato also recommended including the reflection questionnaire mentioned in Appendix D.
 - Within the teacher’s consent form it is not clear when the FootFidgets® is used with the stand-up desk or if it is just the stand-up desk without the FootFidgets®.
- *Procedural*
 - James recommended that it is specified how the SPM results will be shared and with whom. It is the board’s recommendation that Dr. Swinth reviews the results and shares them with the parents and teachers.
 - The board also recommends that the students share the study results only with parents of the subjects.
 - Clarify the devices used by the school only.

- It was not clear if teachers can decide to end the study or how they would make that request.
- Milam recommend that a picture accompany the letter.

Motion on Protocol: A motion was made that Protocol 1213-05 receive approval contingent upon revisions and receipt of approval by the school and a letter from the committee chair, Dr. Yvonne Swinth. Once revisions are made the protocol can be reviewed by Milam. Milam will compose a letter summarizing recommendations noted above. Motion approved.

Review of Protocol #1213-006

Concerns were raised in the following areas:

- *Procedural*
 - Gardner stated that it is difficult to assess the risk of the proposal without a picture of the object.
 - Milam concerned that there is no contingency plan for what to do if injury should occur.
 - Rife wondered if the medical record is actually needed.
 - The board recommended including a picture of the instrument/device along with a clearer explanation of how it works
- *Informed consent and protecting confidentiality*
 - Rife is concerned that there is no discussion regarding confidentiality and protection of the research materials.
 - The board suggests including in the consent form instructions to clients of what to do in case of injury.

Motion on Protocol: A motion was made that Protocol 1213-06 receive expedited approval contingent upon taking out language about the health records along with including a picture of the device and description of the degree of risk of falling by participating in the study. Motion approved.

Milam asked Ferrari if there is boiler plate language regarding health records being subpoenaed and for health data in general being collected? James will send Ferrari language she wonders about.

Milam reported he received email from the IRB chair at Lewis and Clark and they reported their board reviews 2 IRBs each and they decide expedited and exempt status. They tend to receive 3 exempt applications per semester. They have 8 members on their board which includes the community member.

Milam stated that 1 IRB protocol is expected over winter break and maybe a few others. Milam asked if there would be a quorum over break.

The meeting was adjourned at 3:50pm.

Respectfully submitted,

Kirsten Wilbur