

IRB Minutes November 21, 2014

Present:

- Beyer, Tim (co-chair)
- Christensen, Troy
- Elliott, Joel
- Ferrari, Lisa
- Kim, Jung
- Mahato, Mita
- Richards, Brad
- Tiehen, Justin
- Wilbur, Kirsten (co-chair)

Kirsten Wilbur called meeting to order at 8:30 am

Approval of minutes from October 17, 2014 meeting – no corrections – all in favor

The following exempt/expedited protocols were reviewed by members since the last meeting:

- 1415-010.1- approved after revisions
- 1415-018.1- approved after revisions
- 1415-028 - approved
- 1415-009 – approved
- 1415-017 - approved
- 1415-025 - approved
- 1415-034 – approved
- 1415-036 – approved
- 1415-029 – approved
- 1415-039 – approved
- 1415-019 – approved
- 1415-037 – approved
- 1415-006 – approved
- 1415-014 – approved
- 1415-031 – approved
- 1415-032 – approved
- 1415-005 – approved with revisions
- 1415-021 – approved with revisions
- 1415-030 – approved
- 1415-008 – approved with revisions
- 1415-016 – approved with revisions
- 1415-024 – approved with revisions
- 1415-033 – approved
- 1415-011 – revisions requested
- 1415-038 – approved with revisions

Discussed the procedures on what happens with protocols that are revised by investigators. Revisions will go back to the reviewer and the final version is uploaded to shared drive by reviewer

Discussed a particular situation where the same investigator submitted a protocol with 2 different protocol numbers as the original protocol submitted by the student was revised by the faculty advisor and resubmitted to IRB office. The same experiments were described in both applications but the latter had more details. In this case, the reviewer will include both protocols under the original protocol number

Discussed who is responsible for confirming that a protocol is exempt vs expedited. The reviewer has the option to change the category and review accordingly. Jimmy simply sends out protocols as determined by the applicant, but it is ultimately up to the discretion of the reviewer to make the appropriate changes

Discussed the timeframe for communication between reviewer and applicant once the reviewer has contacted the investigator regarding protocol and asking for revisions. Once the first review decision has been sent to the applicant it is up to the applicant to make appropriate changes and submit back to the reviewer

Discussed whether supervisors/advisors have checked the application prior to submission. This continues to be a gray area as once the cover sheet is signed the assumption is that application has been reviewed by all participants. It is hoped that at least one read through has been completed by the advisor/mentor. New language has been added to the revised cover sheet with the statement that when the advisor signs the cover sheet he/she is agreeing that they have read the protocol

Review of full board protocols:

1415-027

Specific questions raised on the protocol:

- 1) Letter from principal?
- 2) Proposal submitted to other IRB? – correct box was checked? Approval letters?
- 3) If research is done at Tacoma public schools need an approved protocol from Tacoma public schools – does University Place have the same procedure?
- 4) Consent forms for principal and teachers are missing
- 5) Consent form letters that are supposed to be sent home to parents is missing
- 6) Estimate of risk based on devices? How do we know? In the past figures of devices or information brochure of devices have been included – it seems that one also should be included here?
- 7) Standing desk – how long will students use the desk, i.e., all day? Does using this equipment induce additional stress? Need to clarify how the devices will be used in the classroom
- 8) Investigator needs to provide detailed information of objects, equipment, etc. used in the study to better understand the risks

- 9) Consent form – participant’s initials? – children’s assent form should be separate from parents/caregivers consent form as the language is not clear
- 10) Under point #3 in Procedures please clarify what assent means
- 11) Page 2 of the consent form – alternative vs dynamic seating – please keep terms consistent
- 12) Confidentiality – withdraw can be done via phone or email, not just in writing – please change

1415-035

Specific questions raised on the protocol:

- 1) On the cover sheet – was this protocol approved elsewhere? Was the box for “submitted elsewhere” checked by mistake? Please clarify
- 2) Why was risk considered “moderate”? What would the procedures outlined in this protocol produce more risk than risks faced during a typical work day? Please clarify
- 3) Under “unfamiliar work positions” the text is written in second person “you” vs “participant”. The explanation of risks need to be clearer – what does it really mean?
- 4) The proposed arm support device is not fully described and needs more clarification. For example, can the investigators provide pictures, drawing, detailed description, etc. The approval of the protocol will be delayed as well as the review until this is completed
- 5) Under “participant checklist” there is discussion about the discomfort level pertaining to “at this moment” – can this be clarified? Some context? Related to pipetting?
- 6) The inclusion of an authorship form in lieu of a signature for Deborah Read seems insufficient. Can the investigators provide an electronic signature or letter from her?
- 7) The advertisement flyer seems inadequate. Perhaps a picture or some illustration describing the study would be helpful?

1415-040

Specific questions raised on the protocol:

- 1) Can the investigator provide a picture of the “Finding Nemo kick gym”?
- 2) Should the guardian keep their hand on the infant during the initial stages of the kicking? Please clarify
- 3) Please clarify why 6 hours and how these opal monitors will be used by the “participants” after the testing procedures?
- 4) It is unclear exactly how the guardians are to mail the opals back. For example should they be returned soon after the 6-hour period? The 13-hour battery life on the opals – if the guardian waits past this 13-hr window, will the data not be useable? Please clarify this section.
- 5) Protocol – benefits – keeping the toy not consistent with consent form
- 6) Under “testing procedures” it seems that the language used for the parents could be softened and written similarly to that of the main text

7) Under “Confidentiality of Data” – using a secure FTP site to transfer data between USC and Puget Sound – what happens with the data at USC? And if the data are already deidentified it seems that the word “secure” is not needed

Questions on the subject recruitment flier:

- 1) Suggest removing language about “down syndrome and kicking **less**” – will a parent “push” their child to do more even if stressed because parents know that DS children kick less? Rather than remove the whole second point – maybe change the language to state “tend” to kick less and unbold “less”
- 2) What about “important” study – is the word “important” necessary?
- 3) Change the logo of the university to new marketing logo

Consent Form:

- 1) Consent form – change to official university logo and then remove the header on subsequent pages
- 2) Page 6 – participants should be informed that they can contact the researcher as well as the associate dean if they wish to have their taping session deleted
- 3) page 4, the language is in 3rd person instead of 2nd person – please change to second person so parents are aware that the language is referring to the child, not participant
- 4) Under “Risks and costs and payment” (page 3) please place language that allows parents to withdraw children from the study at any time under any circumstance

A general question was raised with studies involving children. What is okay and not okay to do with kids? Researchers usually “influence” what parents do in a research setting. Hence how does this set up liability to the university? It is possible that parents will say “we were told to do this” by the researcher

General discussion points on what needs to be done to get Puget Sound-specific CITI training implemented for the campus community

- Helpful if we can start next semester being able to draw in larger number of people to use CITI training
- Having student portions available to those starting methodology course
- Start thinking about training for next IRB group as well as faculty colleagues across the university
- The structure of CITI has some hiccups – some short-cut language was used as is, whereas some came with boilerplate language that was not designed by Lisa Ferrari. Therefore before CITI training for Puget Sound community is rolled out, the site needs a lot of work and edits
- IRB members are being asked to navigate carefully some of the ambiguities, problems, and any material that appears superfluous
- Need to determine how to handle distinction between what IRB members need to know for training vs what average Puget Sound faculty needs to know
- Too many modules for the average faculty member – how to make it better?

- Which modules are more important for faculty researcher? Some redundancy such as the Belmont report where consent is discussed in many different places
- Information in some of the modules not detailed enough – so what do IRB members need to know? All would include 12 modules – but this can also be paired back
- The BIG question: What do IRB members and faculty researchers need to know? How do we make the distinction between the 2 groups?
- The goal is to have these questions answered at the next meeting (December)
- Brad Richards posed the following question: Can the tracks be changed in the system? Lisa Ferrari's response was "yes", but not the modules as most of the modules were accepted from sessions during the summer. Follow-up question: Are there other tracks from other institutions that we can see as examples? How about those that combine biomedical and social sciences? Answer: There are redundancies in these modules but at this time they can not be combined
- These and other points regarding CITI training will be discussed in greater detail at the next meeting

The next meeting will be a full board meeting (if needed) on December 12 in WEY (room TBD) from 8:30-10:30 to allow ample time to review protocols and discuss CITI training requirements and implementation in greater detail.

Meeting adjourned at 9:35 am

Respectfully submitted,

Jung Kim