

IRB Minutes November 22, 2013

Present:

- Beyer, Tim (co-chair)
- Breitenbach, William
- Ferrari, Lisa
- Gurel Atay, Eda
- Houston, Renne (co-chair)
- Kim, Jung
- Wilbur, Kirsten

Tim Beyer called meeting to order at 8:00 am

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

- 1314-013 – approved after 1 round of modification
- 1314-012 – approved
- 1314-021 – approved
- 1314-018 – approved
- 1314-014 – approved
- 1314-023 – approved
- 1314-022 – approved
- 1112-001 – renewal approved
- 0809-007 – CORE renewal approved
- 1314-007 – approved
- 1314-010 – approved
- 1314-008 – approved
- 1314-015 – approved after modification
- 1314-019 – approved
- 1314-009 – approved after modification
- 1314-016 – approved after modification
- 1314-024 – approved

Discussed the responsibilities of the member on protocol and approval summary sheets. Members who review exempt/expedited protocols will upload the following documents into the IRB folder after each review:

- Summary sheets
- Protocol summary sheets which include all amendments and modifications
- All email correspondence between member and investigator

Need to confirm with Jimmy who will upload the final IRB application once all modifications (if needed) are made to the original submission.

Discussed whether the protocol decision document needs to be saved as “read only” so that documents cannot be altered. Further it was suggested that documents could be saved

as PDF. Decision was made to leave the current format as is as only IRB members have access to the folder

Short discussion on how IRB reviews are going for members. Some of the issues raised during the initial conversation include the following:

- 3-day window is not always working. An initial response (does not need to be final) whether the protocol is approved or needs modification needs to be made within 3 days
- if unable to review the protocol then let Jimmy know that you are unable and have the protocol sent to the next member and have Jimmy re-loop you on the next review

This conversation will continue at the next meeting.

Discussed the need to modify the cover page and make sure there is a line for email addresses so that correspondence can happen in the event member is off campus and does not have access to address book.

Discussed whether correspondence between member and investigator should be anonymous during the review to avoid potential conflict. Lisa Ferrari felt that the current procedure of email communication between member and investigator brings more transparency to the process, and to leave as is. Members were in agreement.

Need to make sure that Jimmy does not stamp consent forms unless the final approval is completed. Hence to make sure there are no lapses, members must Cc Jimmy on the final approval email to the investigator.

Below is the summary of the full board review of 1314-007

Investigators Emily Howell-Forbes and Anne James were invited for clarification of the above protocol.

Summary: General questions included clarification of how the dog will be used in the study, the care of the dog, i.e., maintaining nails, use of the head collar, and the unpredictable nature of children and dogs were raised and discussed.

Additional questions on the consent form such as the exclusion policy for children with CP related to distress, the decision to end the research if parents are distressed at any point in the study, and the elimination or merging of consent forms to generate less confusion, the communication options, i.e., phone, email, in-person, to end participation at any point during the study, and the removal of some phrases in the document that appear coercive, and the inclusion of audio visual material and its potential use at future conferences, and the modification of the assent form for minors appropriate to each individual subject also was discussed.

A sample of the script for the phone and/or email to the parents/guardian of the minor was asked to be included in the appendix of the protocol.

The next meeting will be a full board meeting (if needed) on December 13 (time and place TBD) and will go beyond the 1 hour in order to discuss progress and update of outstanding charges.

Meeting adjourned at 9 am

Respectfully submitted,

Jung Kim