Institutional Review Board Minutes January 18. 2007

Members present: Allen, Finney, Kaminsky, McCoy, Ochosi, Preiss, Wilson, Woodward

The meeting was opened at 11:05 AM in Wyatt 326

- 1. Question raised about international data collection and whether or not an IRB application needs to be submitted. The Board felt that if a UPS researcher is involved, an application does still need to be submitted.
- 2. Review of Protocol #0607-005
 - This protocol was resubmitted to the Board with changes made based on IRB review from November 2, 2006.
 - Letter of support has been received from the City of Tacoma
 - Still some questions about how participants will be recruited. The protocol indicates that the potential participants will be asked about the study while the researchers are present. There was some concern that this is coercive. The Board would like potential participants to be asked about the study prior to meeting the researchers.
 - There is nothing in the consent form about police department involvement in the study, but the protocol seems to indicate that the police will be involved with the study. Is that accurate? If so, the consent form needs to be clarified.
 - Need signatures from all researchers on the front page of the protocol.
 - The Board felt that the researchers have addressed the points raised by the IRB in the November meeting.
 - The Board unanimously approved the protocol when these changes have been made.
- 3. Review of Protocol #0607-013
 - This protocol was discussed in the December 7th IRB meeting but was not voted on due to time constraints.
 - The student researcher did an excellent job of addressing the Board's concerns. The Board was informed that the protocol has been approved by MultiCare's IRB.
 - The only question that arose related to when the linking information about participants would be destroyed.
 - The Board unanimously approved the protocol.
- 4. Review of Protocol #0607-014
 - No concerns were raised by the Board.
 - The Board unanimously approved the protocol.
- 5. Review of Protocol #0607-010
 - This protocol was reviewed in the December 7, 2006 meeting and was sent back to the student researcher and advisor for revision.
 - Not all Board members had received and read the protocol prior to the meeting today, so serious deliberation was not conducted. There was some discussion including:
 - This protocol is much improved from the last version

- Based on some language in the proposal (pg4 under subject recruitment), we think there may be some confusion relating to signature of a consent form. Do know that if a person decides to participate, they must sign the consent form; it is not an option. Perhaps the researcher meant that at the time the researchers talk with the potential participant, he/she still has the option to decline to participate.
- On the consent form the researcher's contact information needs to be included in the voluntary consent section.
- Some discussion about whether or not inclusion criteria can be expanded to include anyone with a diagnosis of CRPS rather than people with a diagnosis of UE CRPS only. This may help with recruitment.
- Some discussion about the use of the word "affected" in the interview questions. Is it possible to eliminate this word since it implies victim language? Suggestion was to use "right" or "left" limb depending on diagnosis.
- Exclusion criteria: what about other diagnoses, including other diagnoses with pain, cognitive diagnoses?
- The Board recommends asking about other medical history and medications that may complicate the data.
- Why can't tapes be destroyed after transcription? (Since they are identifying data.)
- The researcher indicates that interviews will use open ended question, but most of the questions supplied in the interview protocol are closed ended questions.
- On the consent form, some of the language is too complex and uses jargon that is not likely to be easily understood by participants.
- In addition to not using names, the researcher should not use other information that can be used to identify participants. A statement to that effect should be included under the "confidentiality" section of the consent form.
- On the letter that will be sent to clinics, there is a typographical error. The second point "c" should be changed to a "d."
- 6. Some discussion about when regular IRB meetings will be held during spring semester. Tentative meeting date was set as Friday, February 2nd from 12:00 to 1:00, but this will need to be confirmed with all IRB members.
 - Since the 1/18/2007 meeting the dates for the IRB to meet this semester have been determined, Thursdays 11:00-12:00, for the first Thursday of the month with the exception of February. The meeting dates are: February 8, March 1, April 5 and May 3, 2007.
- 7. Strategy for reviewing guidelines discussed. Wilson recommended dividing up the guidelines and assigning each member a section to thoroughly review. McCoy will make these assignments.
- 8. Some discussion about when IRB approval is needed for research that takes place as a part of regular course work. The Board feels that if students are going off campus or are asking questions of a sensitive nature, IRB approval should be sought. A suggestion was raised that students enrolled in research classes go through an online training course about protecting

human subjects (e.g. <u>http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp</u>)

The meeting was adjourned at 12:05 PM.

Respectfully submitted, Tatiana Kaminsky, IRB Secretary