Institutional Review Board Minutes
December 7, 2006

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

The meeting was opened at 3:00 PM in Wyatt 226

1. Meeting in January
   - Board needs to meet in January to attend to protocols that are being revised and new protocols submitted. Will meet on Thursday, January 18th at 11:00 am. McCoy to arrange meeting room

2. Introduction of community representative
   - The Board welcomed Marsha Gallacher as community representative.

3. Question raised about a study that was completed several years ago. A secondary analysis is currently being completed with those data. If the researchers want to collect follow up data, do they need to submit a new protocol? The Board felt that the researchers did indeed need to submit a new protocol for review.

4. IRB Stamp
   - Stamp has arrived and was proudly displayed. All IRB approved materials including consent forms and recruitment flyers, will be marked with the approval stamp from now on.

5. Update on previously discussed protocols
   - #0607-005 – City of Tacoma has submitted a letter of support. The revised protocol has not yet been resubmitted. The Board will review the revised protocol when it is received.
   - #0607-006 – nothing new to report
   - #0607-007 – This protocol was revised according to the Board's recommendations and was approved.
   - #0607-009 – Finney and Preiss determined that this protocol was more suitable for expedited review than full board review. They approved the protocol rather than bringing it to the full committee.

6. Review of Protocol #0607-008
   - Some minor revisions to the protocol were made by the researchers based on feedback from the IRB in the November meeting.
   - Change benefits of participating in study on consent to say that there are no immediate benefits to participants.
   - Under the HIPAA statement, change word "disclosed" to "shared" to be consistent with the approved HIPAA statement.
   - There is a typo on the last page of the consent. "as" should be changed to "was"
   - Change type on visual analog scale to be less pixilated
   - Some changes recommended for medical questionnaire:

    - Pacemaker or other medical device should be more prominent
    - Correct numbering
    - Change first #9 item so that medical conditions are listed separately to improve ease of use of questionnaire
    - Change second #9 to ask participants if they are pregnant or trying to become pregnant
- The Board approved this protocol with the above changes.

7. Review of Protocol #0607-010
    - The Board determined that this protocol is not yet ready for review by the IRB. There are several areas of concern, some of which are listed here. The student researcher and faculty advisor need to review the protocol thoroughly. Some of the issues include:
        - The Board recommends the collection of more demographic data, including time of onset, how long participant has had CRPS, other treatments tried
        - HIPAA statement should be included since this study asks for medical information
        - Language in consent is too technical and needs to be simplified.
        - The Board needs a copy of the letter that will be sent to clinics
        - Need more information about how participants will be approached. The protocol as it stands right now does not include details about intermediaries.
        - More information about how tapes and transcripts will be secured, and when data, including tapes, will be destroyed.
        - Researcher's phone number is needed on the consent form.
        - Advisor's name and credentials are needed on the consent form
        - Consent form needs to say how long the second interview will be.
        - The Board suggests removal of the "new information" section on the consent form.
    - The Board agreed to send the above recommendations to the researchers and consider a revised protocol after it is submitted to the IRB.

8. Review of Protocol #0607-011
    - The questionnaire that will be given to participants needs to be submitted to the Board.
    - The Board requests letters of support from the therapist in Iran who will be administering the questionnaires and from the facility in which the research will be conducted. Qualifications of the researcher in Iran are also requested.
    - There were some questions about human subjects regulations in Iran and the informed consent process. The Board does not know if these are comparable to the regulations in the United States. Will the researcher need to go through an IRB in Iran? How will the researcher ensure that consent is voluntary given the vulnerable nature of this population? How will participants be approached?
    - There were some questions about the reliability and validity of instruments that were developed for populations in the United States for the population in Iran.
    - There was some discussion about sending information, especially sensitive information, internationally. How will this information be protected? How will it be secured in Iran?

- The Board agreed to send the above recommendations to the researchers and consider a revised protocol after it is submitted to the IRB. Additionally, it may be helpful if the researchers attend the next IRB meeting to help answer some of the Board's questions.

9. Review of Protocol #0607-012
   - What behaviors will be monitored to determine if a child does not want to continue participation in the study? The Board suggests that these be added to the protocol.
   - Parent's consent form should be restructured slightly to indicate what will be done with the child during the study.
   - Some discussion about the language in the assent and whether or not it was too sophisticated.
   - The Board recommends some modification to the recruitment flyer. The flyer is visually confusing. In addition, the language is too technical. Finally, the researcher's personal phone number should not be listed as the contact number.
   - The Board approved the protocol with the above changes.

10. Discussion on Protocol #0607-013
    - The protocol was not thoroughly discussed due to time constraints. Several points were raised that will be shared with the researchers:
      - More detail is needed about what treatments will include. It is difficult to determine risks for participation in the study without this information.
      - What is SIPT and how is it done?
      - HIPAA statement needs to be included in the consent.
      - Some discussion about coordinating with MultiCare IRB, which may want UPS IRB approval first before considering the protocol. The Board also wondered if the researcher was aware that MultiCare IRB charges $1500 per review.
      - If participants will be paying for treatments received during the study, does that mean that the control group will pay more than the experimental group?
      - Child assent needed.
      - The researcher needs to submit the questionnaires for the control group in addition to the questionnaires for the experimental group.
      - Some questions raised about whether or not participation in the study will move people off of the waiting list earlier than they would be otherwise. Some concern that this may be coercive.
    - These concerns will be shared with the researcher. The Board will consider this protocol in more depth on January 18th.

11. McCoy would like all Board members to complete an IRB training course with which she is familiar. She will send out the link to Board members.

The meeting was adjourned at 4:06 PM.

Respectfully submitted,
Tatiana Kaminsky, IRB Secretary