Institutional Review Board Minutes
May 6, 2004

Members present: Allen, Coogan, Foster, Preiss

The meeting was opened at 9:16 AM in Collins Memorial Library.

1) Minutes of the April 14, 2004 meeting were approved.

2) Review of Protocol #0304-015

This protocol is being revisited since receipt of requested additional information.

The following issues were raised by the Board:

- Regarding the consent form:
  a. Type in the investigator's name below the signature line.
  b. The investigator is not to presign the certification. However, due to the manner in which consent is established in this study, the investigator's certification section is not necessary and may be eliminated.
  c. The investigator may elect to add wording to the consent form indicating that "By completing the questionnaire, I acknowledge consent:" in lieu of requiring signed consent from each subject. This is to eliminate the potential difficulty of obtaining an unequal number of consent forms and completed questionnaires.

The study was approved pending receipt of the above corrections by the Office of the Associate Dean (4-0-0).

3) Review of Protocol 0304-019

The following issues were raised by the Board:

- In the introductory section, please explain what "nemaline myopathy" is and what the significance of the related study is to the proposed research.
- In the consent form, please correct the phone number of the Associate Dean to (253) 879-3207.
- Further explanation is required in the methods section regarding muscle length and muscle strength testing. The Board recognizes that specific tests cannot be predicted at this time due to the variability of conditions that may be manifested in individual participants. The Board also recognizes that all assessments will be consistent with the regular implementation of physical therapy for each participant's condition. However, rather than simply referencing each type of assessment, please provide one or two sentences in the protocol describing how muscle length and strength testing is done.

- Describe a plan for handling participant attrition. How many missed clinic recheck visits, or consecutive missed recheck visits will be cause to eliminate a participant from the study?
- In the event a patient does not return for scheduled rechecks, how will the investigators determine if the missed appointments may or may not be due to a negative or harmful response to the treatment under investigation?
- Describe a plan for assessing adherence to the exercise prescription. Also describe how no-shows and cancellation of recheck visits will be handled. Will reminder calls be made? Will follow-up calls for missed appointments be made?
- Monitor any changes in medication dosage throughout the course of the study and describe in the revised protocol how that monitoring will be done.
- On the medication screening questionnaire, ensure that participants report any over-the-counter medication usage, specifically anti-inflammatories and analgesics.
- Describe in the revised protocol how the normal pain (or any other symptoms) associated with remobilization and reactivation will be distinguished from pain symptoms that may indicate the dosing protocol is causing further damage to the injured area.

The study was approved pending receipt of a revised protocol that addresses the above issues by the Office of the Associate Dean (3-0-1).

4) Review of Protocol 0304-020

The following issue was raised by the Board:

- For a protocol of this length, it would be most helpful for the investigators to number the pages.
- On the cover page, indicate that no children will be involved as participants.
- Of the "open ended questions" presented in Appendix C4, few are actually open ended. Please change the title of this question list to simply "Questions."
- The SF-36 is proposed as the functional inventory. This inventory is now the Rand-36. Rand has made available several shorter versions of this inventory, all the way down to the Rand-8. Given the length of the entire battery of assessments and the real possibility of participant fatigue, the investigators are encouraged to look into the appropriateness of one of the shorter versions of the functional inventory for use in this study.
- The faculty advisors letter is to be signed.
- The last line of text from the facility consent form in Appendix D2 should be eliminated.
- The facility consent form text should begin with wording such as "I the undersigned affirm that I have authority to approve participation of this facility in the proposed research activity."
- When signed, a copy of the facility approval letter must be forwarded to the Board, in care of the Office of the Associate Dean.

- In the consent form the phone number of the Associate Dean should be corrected to (253) 879-3207.
- In the consent form the wording “sensitization to mood” should be altered to make the language more readily comprehensible to potential participants. One suggested alternative wording would be “potential mood changes.”
- Given the possibility of visual impairment in potential participants, the font size on the consent form should be increased to reasonably allow participants to clearly read the text.
- In the revised protocol, describe what information will be provided to potential participants when they are first introduced to the investigator and to the study. The Board encourages the development of a standard script.

The study was approved pending receipt of a revised protocol that addresses the above issues by the Office of the Associate Dean (4-0-0).

5) Review of Protocol 0304-021

The following issue was raised by the Board:

- On the consent form include language stating that exercising the right to refuse or discontinue participation in the study will in no way affect your participation in the workshop or credit you may obtain for attending.

The study was approved (4-0-0).

6) Recommendations for next year's Faculty Senate charges to the IRB were discussed. Those included the following:

- Update the IRB website.
- Consider support of the IRB chair with release time.
- Explore the practical implementation of compliance checks with people outside UPS who may have expertise or experience with systems for oversight of research compliance.

7) The meeting was adjourned at 10:25 AM.

Respectfully submitted,
Roger Allen, IRB Secretary