

Institutional Review Board Minutes
April 14, 2004

Members present: Allen, Coogan, Finney, Preiss

The meeting was opened at 9:00 AM in Collins Memorial Library.

1) Minutes of the March 10, 2004 meeting were approved.

2) Review of Protocol #0304-015

This protocol arrived for full board review missing several elements essential for IRB review. Specifically missing was the consent form, the "Fact Sheet," and no copies of the questionnaires or assessments. It was further noted that the departmental designee did not have the opportunity to review the protocol prior to submission for full Board review. The absence of the questionnaires intended for use does not give the Board adequate minimum information necessary to review the protocol at this time.

The protocol will be returned to the investigators along with a request for additional information.

3) Review of Protocol 0304-016

The following issues were raised by the Board:

- The investigators are requested to elevate the anticipated risk level to "moderate."
- Upon approval by the IRB, or similarly designated entity at the clinical facility where treatment and data collection will be done, the investigators are requested to provide the UPS IRB with a copy of that site's approval letter.
- In the consent form, please correct the telephone number of the Associate Dean to 253-879-3207.

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

4) Review of Protocol 0304-017

The following issue was raised by the Board:

- The investigator is instructed not to presign the "investigator's certification" on the consent form.

The study was approved (3-0-1).

5) Review of Protocol 0304-018

The following issue was raised by the Board:

- Prior to beginning subject recruitment and data collection, the investigators are instructed to provide the IRB with letters of project approval and consent to use that facility's patients as research participants from any and all clinic sites whose patients may be participating in the study.

The study was approved (3-0-1).

6) The next meeting date of the IRB will be May 6, 2004, at 9:00 AM.

7) The meeting was adjourned at 9:35 AM.

Respectfully submitted,
Roger Allen, IRB Secretary