Institutional Review Board Minutes December 15, 1998

Present: Wilson (Chair), Finney, Holland, Moore, Preiss, Wadsworth, Wells

Wilson opened the meeting at 9:05. Preiss distributed the minutes of the November 17, 1998, meeting. Without correction, the minutes were read and approved.

Protocols considered:

9899-002-Modification: Wilson reviewed the protocol, listed the concerns communicated to the author, and summarized modifications in the protocol resulting from the review process. A discussion ensued. It was concluded that the new balance test (Get-Up-And-Go) responded to all IRB concerns. Minor suggestions were made regarding the format of the protocol.

Approved: Vote, 7 Yes, 0 No (pending modifications)

9899-005: Members expressed a desire to see greater clarity regarding the writing assignments, simpler wording in the consent form for children, a detailed description of the "grasp task," and a specified location for storage the writing samples.

Approved: Vote, 7 Yes, 0 No (pending modifications)

9899-006: Members agreed that the Informed Consent Form should be on university letterhead and that the addresses and phone numbers of the university and the host institution should be included on the Informed Consent Form.

Approved: Vote, 7 Yes, 0 No (pending modifications)

9899-007: Members agreed that the parents' Informed Consent Form was too complex. Alternative phrasing was suggested and it was noted that the Consent Form did not indicate who would be signing the form.

Approved: Vote, 7 Yes, 0 No (pending modifications)

9899-008: A discussion of the protocol revealed several errors and gaps in reporting. Wilson was instructed to contact the author(s) with directions to insure consistency between the methods section and the Informed Consent Form, clarify the number of sessions, and clarify the use of weighted wrist treatments. Also, clarification was requested regarding the process for determining participant competency in making informed consent.

Vote for No Action: 7 Yes 0 No.

Wilson directed members to a discussion of the spring schedule. It was decided to convene the IRB on the fourth Tuesday of each month (January 26, February 23, March 23, April 27).

Wilson called for a discussion of the IRB web page. The discussion centered on frequently asked questions.

Wilson asked for new or old business. Hearing none, she adjourned the meeting at 10:05.

Respectfully submitted,

Ray W. Preiss Secretary Institutional Review Board