IRB Committee Minutes
September 2, 2004

Members present: Roger Allen, Patrick Coogan, Lisa Ferrari, John Finney, Robin Foster, Kathi Lovelace, Yvonne Swinth, and John Woodward.

Business

1. Roger Allen was elected Chair for 2004-2005.
2. Robin Foster volunteered to serve as secretary during the fall term, and Yvonne Swinth volunteered to serve as secretary during the spring term.
3. This fall the IRB will meet from 8:00-9:15 am on October 7, November 4, and December 2 in Wyatt 326.
4. To ensure timely review of proposals that require a rapid turn-around and whose submission does not coincide with the scheduled IRB meeting dates, committee members agreed to ad hoc meetings facilitated by electronic discussion of salient issues.
5. Monitoring IRB approved projects.
   - Roger, John W, and Robin agreed to prepare a standardized document that investigators would complete at the end of a study or after one year. Suggested purposes of the document include: (1) to monitor compliance to procedures outlined in the proposal; (2) to track the outcome of procedures that involve risk; and (3) to record any modifications made from the originally proposed procedures.
   - Requests for follow-up information about concerns unique to a given proposal (especially those involving high levels of risk) could be included as part of the initial notification of IRB approval.
   - A suggested format for the document included checklist items as well as open-ended questions.
6. IRB Webpage. Committee members were charged to look over the IRB home page and suggest improvements by the October meeting.

Proposals Reviewed: The IRB committee reviewed one protocol (#0405-001).

Protocol #0405-001. Approved 4-0-0 (note: two IRB members left prior to the vote)
This project proposed to test the efficacy of an orthotic device on sitting, standing, and walking functions in children with cerebral palsy. The committee discussed the following issues:

1. *Child consent form*. One IRB member questioned whether all child participants would be cognitively/physically capable of providing informed consent in a manner consistent with the child consent form included in the proposal.

   The committee agreed that rather than having a "consent" form for the child to sign, an "assent" form should be provided that specifies nonverbal behaviors related to participation that the investigators/therapists will use to

determine if the child wishes to participate or discontinue participation in the study.

2. *Further clarification of falling risk and prevention*. IRB members agreed that the most serious risk involves potential injury from a fall. Further clarification on responsibility and measures taken to prevent falling is needed in several sections of the proposal. Page 5, "Risks to Subjects" states that "Children will be closely monitored", but does not clarify who will be responsible for monitoring the children. The consent form "Risks and Benefits" section states that the "risk [of falling] in this study is small because [the parent] may stand and walk by your child during each test." However, the researcher is responsible for fall prevention; the parents' close proximity may rather have psychological benefits to the child.
3. *Clarification of orthotic device benefits.* The informed consent states that, "If the [orthotic] is beneficial for your child, he or she may keep [it]." How and when would a parent know whether the SWASH was beneficial?
4. *Host site approval*. Committee members agreed that UPS will not be signing the form from WIRB that would formally transfer jurisdiction to UPS. Instead, it will be up to the host clinic site to determine if UPS approval of the protocol is sufficient to allow the study to be conducted at their facility.

Respectfully submitted 9/2/04
Robin Foster