

**MINUTES**  
**Institutional Review Board**  
**December 1, 2009**

**Present:** Garrett Milam (Chair), Lisa Ferrari, Mary Rose Lamb, Grace Kirchner, David Luper, and David Moore

Meeting was called to order at 8:20 a.m.

**Announcements:** Garrett reviewed the agenda for the meeting and explained that the OT designate would be present for the latter part of the meeting to consult on the two protocols under review. Garrett also announced that there may be additional protocols coming in (particularly from the OT program) during the interim between semesters, and he suggested the possibility of holding a meeting in January over the holiday break. It was decided to defer discussion regarding the necessity of holding such a meeting until after talking with the IRB designate from the OT program.

**Orders of Business:**

**1. Deliberation on Protocol 0910-004.** Key issues and questions included the following:

- More information is needed regarding specific procedures to protect confidentiality and potential limits or barriers to protecting confidentiality of the participants, given the highly publicized nature of their case.
- Separate consent forms for publication should be added, which would be given to participants after they have a chance to review the information in the interview transcripts and write-up.
- The researchers should have an explicit procedure for making referrals for psychological services or intervention, if needed or requested by participants.
- It was felt that the language in the patient's consent form should be changed to be a bit more developmentally appropriate for an adolescent (in its present form, it seemed more appropriate for a younger child).
- It is recommended that an additional consent form (separate from the one for the Certified Hand Therapist) be adapted specifically for the parents.
- A letter of support from the clinic should be included.
- More information is requested on the questions (or at least key themes and issues) that the primary investigator plans to ask in the interviews for both the adolescent and the parents.

The protocol was discussed briefly with the IRB designate from OT.

**Action:** M/S/P The protocol was unanimously approved (6-0), pending the requested revisions.

2. **Deliberation on Protocol 0910-005.** The committee raised the following issue:

- In order to further safeguard confidentiality when surveys are returned via the mail, it is requested that the researchers include 2 separate return envelopes for consent forms and surveys, respectively. This could ensure that participants survey responses are kept separate from identifying information included on the consent forms.

The protocol was discussed briefly with the IRB designate from OT.

**Action:** M/S/P The protocol was unanimously approved (6-0), pending the requested revision above.

3. **Handling of Interim Protocols.**

The IRB designate from OT indicated that she anticipated at least 2 protocols needing in need of Full Board review during the holiday break. The reasons for these late submissions were discussed briefly, and the designate explained that the submission timing was an artifact of the OT curriculum rather than procrastination on the part of the student researchers. Regarding handling of these protocols, the committee discussed the tentative plan to review these protocols at least initially via Email, with the goal of potentially facilitating any necessary revisions to the protocols before final approval could be given, either in an interim meeting, if necessary, or as early in the spring semester as possible.

The meeting was adjourned at 9:30 a.m.

Respectfully submitted,

David Moore