

IRB Committee Minutes
5 December 2005

Members present:, Patrick Coogan, Lisa Ferrari, John Finney, Leon Grunberg, Kathi Lovelace, Ray Preiss, Sally Westcott, and John Woodward.

I. Business

1. IRB members approved the November 7 minutes.

II. Proposals Reviewed

The committee reviewed four protocols (#0405-006 through 0405-009).

1. Protocol #0506-002.

Decision: Approval pending revisions.

The purpose of this project is to investigate sibling relations and some of the more subtle aspects of children's development. The committee initially noted the absence of attempts to get IRB approval from the school or school district. This needs to be in place before proceeding. The title of the Patty McClelland should be on the parent letter. The parent letter should indicate that the data will be kept for only 3 years. The committee suggested that there might be some risk to the students insofar as the students will be asked about parental conflicts. This might possibly provoke discomfort in some students. This should be included in the consent form. The student letter should indicate that they can quit at any time and that there will be no consequences (e.g., no one will be mad at you). Also, the committee suggested that children should get gift bags regardless of whether or not they complete all questions. There was also a concern for privacy when students complete the questionnaire. Researcher should make an effort to have students complete the questionnaire in ways that their answers are private (e.g., conducted in the school cafeteria, library). Consent and assent forms should have the researchers' names on it.

2. Protocol #0506-003.

Decision: Approval pending revisions.

The purpose of the study is to investigate the role of humor in therapy. Once the study is approved through St. Joseph's IRB, they should send a copy to the university's IRB. The applicant should clarify exactly under what circumstances audio taping will occur. We understand at this point that only the interviews will be recorded, but we need to clarify this point.

The audio taping should be included on the consent forms as well as the script read to the participants. One minor concern is the title of the study on the consent forms – Just Kidding. This might be a little to lighthearted.

3. Protocol #0506-004.

Decision: Approval pending revisions.

The purpose of the study is to investigate the effects of a splint on weight bearing activities involving the arm. A more exact estimate of time for taking measurements should be stated the parent consent form. The applicant should make it clear on the consent forms who will make and apply the splint and that the costs will not be charged to the parent. The applicant should return a revised application containing a picture and a timeline for the way the phases will occur.

4. Protocol #0506-005.

Decision: Approval pending revisions.

The purpose of the study is to investigate the impact of primary lymphedema on an infant's daily life. The word infant appears in the application, and it appears that the age of the individual is better described as a child. The committee felt that it would be clearer if "child and sibling of the child" were used in the application. The parent consent form should mention that a third party will transcribe data collected for the study. The title on the child's consent form should be less leading.

The meeting adjourned at 2:59.

Respectfully submitted 12/14/05
John Woodward