## IRB Committee Minutes 2 December 2004

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

## I. Business

1. IRB members approved the November 4 minutes with minor corrections.

## II. Proposals Reviewed: The committee reviewed four protocols (#0405-006 through 0405-009).

1. Protocol #0405-006. Decision M/S/P Approval with revision.

The purpose of this graduate student project is to investigate the meaning of rehabilitation from stroke using interviews and observations. IRB members asked for the following revisions: (1) include a project title on the cover page of the protocol; (2) clarify the criteria for inclusion and exclusion in the study; (3) address whether consent from a legal guardian is needed for adult participants unable to give consent for themselves, and if so provide such a consent as an addendum; (4) clarify the time frame for the use and destruction of videotapes of interviews, and to be clarify the videotape use in the informed consent; (5) clarify the timing of follow-up interviews.

2. Protocol #0405-007. Decision M/S/P approval, pending submission of modifications as stated below and in a letter sent to the investigator.

This graduate student project proposed to study play and its meaning in children with autism. The student's advisor presented revisions to the written submitted protocol in person, the results of which were to simplify the study and increase the project's feasibility, without affecting its risks to participants. The IRB approved the revised protocol, contingent on its submission in written form to the Associate Dean. These points of revision included (1) changing the definition of family; (2) removing focus groups from the procedure; (3) limiting interviews to family; (3) conducting observations in the home, leaving open some possibility for observations in the clinic; and (4) modifying the therapist's consent form to match revised procedures.

3. Protocol #0405-008 Decision M/S/P approval of protocol with a request for minor revisions as stated below and a letter sent to the investigator.

The purpose of this graduate student project is to investigate the effect of proprioceptive exercise involving resistive movement such as push-ups, squats, and hand-pulls, on levels of aggression in elementary school aged children. The protocol will also equire IRB approval from the school district. Issues of feasibility were raised by IRB members, who (1) expressed concern that the investigator would not see changes in students' aggression within the proposed time frame, and (2) wanted clarification on the number of students/classrooms

that would be observed. (3) IRB members also requested that "child" be replaced with "student" on all of the consent forms.

4. Protocol #0405-009. (Note: This protocol was a modification and resubmission of protocol 0405-004). Decision M/S/P approval pending revisions as listed below.

This student project proposed to study attitudes toward HIV testing among young adults who frequent a local youth center. The project received strong support from the youth center. This is a revised protocol, and committee members applauded the student's polite and professional responses to IRB suggestions. IRB members requested revisions to the protocol that were primarily structural, and included (1) correcting and completing the cover sheet ("new project", advisor' name, and check yes to community agency question, with inclusion of the approval letter); (2) detailing procedures about how participants will be recruited; and revisions (3) revising the survey by removing the associate dean's contact information from the cover page (one IRB member noted that filling out a survey indicates consent, and as such a separate consent form is not necessary) and defining the terms "anonymous" and "confidential" on question 9.

## **III.** Other Business

1. NCAA survey.

The NCAA conducts an annual survey of athletes on drug use opinions and behaviors. IRB members concurred that the committee could not approve the proposal without a formal written protocol, but agreed to look at existing materials in order to make recommendations for future proposals.

Questions raised during the deliberations of this request included clarification about how the information would be used, whether UPS IRB approval was required or recommended, whether UPS was required to participate in the survey to be part of the NCAA, and whether the NCAA representative on campus or the NCAA itself should submit the protocol.

The meeting adjourned at 9:02. The next scheduled meeting of the IRB is Thursday February 3, 2004 from 11:00-12:00.

Respectfully submitted 2/02/05 Robin Foster