

**Institutional Review Board Minutes
December 3, 2001**

Members Present: Allen, Coogan, Finney, Ferrari-Comeau, Kay, Lamb, Stewart, Wells, Woodward

0102-009 The committee discussed the possibility that if students talked about their homework in public, they might be embarrassed. However, this information will be documented through a paper and pencil survey, thus making the information private. Protocol approved based on additional parental form, which was missing.

0102-008 There was concern about the content and duration of the interview. Fatigue was another concern. The main issue has to do with themes that would guide the interview. There was further discussion about the ability of the respondent to communicate in the interview(s). The committee would like to have information on how the subjects will be interviewed with sample questions. Also, the committee would like clarification as to the uses of audiotapes beyond the study (e.g., presentation, publication). We also need a copy of the IRB approval from the sponsoring institution. The protocol was approved pending revision.

0102-007 There was a concern with the capacity of the subjects to sign forms in a competent manner. It was unclear if the caregiver was in a legal capacity to sign for the subject. Whether or not the caregiver is a legal guardian remained an open question to the committee. The last form needs to be revised with the issue of the participant's and legal guardian's signature in mind. The advisor's letter needs to reflect the contents of this specific study as well. As written, it is a general letter of support. The protocol was approved pending revision.

0102-003 One member was concerned about the inclusion and exclusion criteria. Also, a concern was raised about the unnatural character of the settings and the observations. This was not a major concern, but it is reflected in the "Risks and Benefits" section of the participant consent form (i.e., "There are no known risks involved with this experimental procedure, other than those of regular daily life."). The committee suggested that the first sentence be changed to, "You will be asked to perform tasks that are developmentally appropriate and are everyday in nature. We know of no risks associated with these tasks." The protocol was approved pending revision.

0102-004 The committee recommended amending the cover page to reflect that the children are not normal. One member suggested that the researchers be more explicit about the intervention techniques in the consent form (yes for adults, no for children). Also, the extent of the commitment should also be mentioned in the consent form. The applicant also needs to mention what will happen to the videotapes at the completion of the study. This needs to be mentioned in the consent form. The protocol was approved pending revision.

0102-005 Amend the cover page to reflect that the children are not normal. One member suggested that the researchers be more explicit about the intervention techniques in the consent form. In this case, the parents may not be normal, so this may need to be qualified. One way to address this is to check both boxes (i.e., yes and no). The consent form needs to be amended for consistency. Currently, the terms "one" and "three" to 24 months are used in the protocol. A sleep record needs to be added to the consent form. Some committee members found that the quotes around "teaching session" were slightly problematic. The quotes should be removed or the term should be qualified. Under the confidentiality section, the writing should be in the third person. The protocol was approved pending revision.

0102-006 A question was raised about the confidentiality of the data. The member suggested that "After 5 years" should be replaced with "Within."

Meeting adjourned at 2:45

Respectfully submitted,

John Woodward

John Woodward, IRB secretary