

# Institutional Review Board Minutes

## April 24, 2002

**Members Present:** Allen, Coogan, Finney, Kay, Stewart, Wells, Woodward

**Opening Business:** The committee established procedures whereby an IRB member who submits a protocol may comment upon the protocol and clarify issues. However, the member may not participate in the vote on the protocol.

0102-011 This protocol was approved with modifications.

0102-012 The protocol was problematic because the survey contains a number of questions about criminal behavior. Many were concerned about how the company might be interested in data from the survey and respond in an untoward manner. Other concerns had to do with the length of the survey (i.e., it may be too long for 10 minutes), the extent to which the sample might actually be random, and the logistics of collecting demographic data. The committee would also like to see copyright permission from Peters and O'Connor and have the consent form revised in a number of ways. The protocol was approved pending modifications.

0102-013 One member expressed concern about location in which the interviews will take place. A coffee shop may not be the most anonymous settings. The committee suggested that the statement about possibility of court subpoena of records in the confidentiality section should be added to the risk and benefits section. This protocol was approved with minor modifications.

0102-014 The committee would like to see IRB approval from Madigan Army Medical Center. The applicant should change the fliers so that they were less likely to lead the subject into believing this study will "lead to treatment and prevention of pain in pregnancy." There was an additional concern about how subjects will be selected. We suggest that contacting people individually or personally should not be part of the process. The protocol was approved pending modifications.

0102-015 Some of the information to potential applicants might be too technical. We suggest that the consent form be changed so that it is less technical. We also suggest that the applicant get permission from locations where fliers are being posted. This protocol was approved with minor modifications.

0102-016 There were no attached approval letters to this protocol. Those need to be in place for the study to proceed. Also, the phone number for the dean is incorrect. The right to refuse should include both parent and child as part of the language. The participant signature should be a parent or guardian signature. We also noticed that there was no flier in the protocol. This protocol was approved pending modifications.

0102-017 The committee discussed the issue of liability for any potential injury. It was not clear how compensation could be addressed in this context. The applicant suggested

the possibility of changing the consent form to address this concern. One member advised that a lawyer examine any changes to the "no compensation for physical injury or illness" before this consent form be used. This protocol was approved with minor modifications.

0102-018 There was a concern about the consent form and its technical language. This form should be changed so that it is more readable to the potential subject. The protocol is unclear in its use of terms like apparatus, tool, and instrument. Apparently, these all refer to paper and pencil measures. This should be addressed in a revised version of the consent form. We would like to see approval letters from every site where this study will be conducted. The applicants have proposed to work with a large number of subjects. More needs to be said about the exclusion criteria in the protocol. This protocol was approved pending modifications.

Next meeting will be scheduled sometime in May. Roger Allen will contact committee members later about the specific date and time.

Meeting adjourned at 10:45

Respectfully Submitted,