

Institutional Review Board
April 7, 2011

Present: Lisa Ferrari, Anne James, Mary Rose Lamb (Chair), Julia Looper, Andrew Rife, Alexa Tullis
The meeting was called to order at 8:00 am.
The minutes of the March 24th meeting were approved.

Review of Protocol #1011-013

- Committee members felt that this proposal has several concerns. Concerns addressed included data storage and confidentiality, how best to gain consent, and recruitment. The board members were concerned that the data storage described in the protocol may lead to a breach in confidentiality and put participants at risk. Given the data storage concerns, location of the study, and ability of the subjects to read English, the board members also discussed whether written informed consent was appropriate in this situation. The protocol would also benefit from a more in depth description of recruitment techniques.

Action: The protocol was not approved but the applicant was invited to consider the boards concerns and resubmit the proposal. 5- not approved 1-abstained

Review of Protocol #1011-014

- Committee members reviewed this study and had several questions. These included data collection issues, confidentiality, and consent form questions. Specifically, the board was concerned about collecting data on subjects who were not technically part of the study. The members also had a question about the actual length of the study. Confidentiality concerns related to data coding, storage, and destruction protocol. The consent form appeared minimal with a debriefing at the end of study participation. Because there is no deception involved in the study, the board feels that the debrief information should be included up front in the consent form. Additionally, board members were concerned about language in the risk to subjects section of the consent form which may give the participants the wrong impression about what will happen to their data. Finally, a child consent form should be included.

Action: The protocol was unanimously approved with revisions. The chair will review the revisions for final approval.

The meeting was adjourned at 9:10 am

Respectfully submitted,
Julia Looper