

Institutional Review Board
March 13, 2008

Present: Roger Allen, Jim Evans, Lisa Ferrari, Tatiana Kaminsky, David Moore, Karim Ochosi, Ray Preiss, Ann Wilson

The meeting was called to order at 9:00 a.m.

Protocol Reviews

0708-012 The board made several suggestions regarding minor modifications to the wording in the consent form including having separate forms for parent consent, minor assent and consent for participants over the age of 18. In addition the board recommended revising the protocol to include a specific plan for allowing participants to opt out and a description of how the researcher plans to keep the study information confidential.

ACTION: The board voted (8-0) to approve the protocol with modifications. Allen will provide the researcher with detailed information and will review the revised protocol to ensure that all of the concerns have been addressed.

0708-013 The board determined that this protocol poses greater than minimal risk as it is currently written. The purpose for conducting both an interview and having participants complete a survey was unclear. There was significant discussion as to the researchers' intended purpose, the proposed participant and data collection methods and the overall impact of the study on potential participants.

ACTION: The board voted (8-0) that it was unable to make a determination on this protocol based on the information provided. The researcher will be asked to revise and resubmit the protocol addressing the specific questions that were raised in the deliberations.

Mechanisms for reporting and follow up on approved protocols – Ferrari inquired as to how the board handles and tracks follow up and closure on approved protocols. This information is necessary to be in compliance with federal guidelines. Allen shared a form that he designed entitled “Informational Follow-up IRB Approved Research Report” which he sends to researchers at the time he sends the approval letters out. These forms are to be returned and archived with the original protocols in the Office of the Associate Deans. There was significant discussion about how the form was currently being used and if there was a way to streamline the process and allow for better reporting from the IRB should the need ever arise. The board decided that the form could be sent to researchers electronically and the information from the completed form could be entered into a database for ease in collating the information. The board voted to devote one meeting a year to reviewing these closure reports.

While the current document covers those protocols that are reviewed and approved by the full board, it does not cover protocols that are reviewed and approved by department designates. The board decided to have the department designates send the same form out to researchers whose protocols were reviewed that level and to have that information sent to the Office of the Associate Deans for archiving and tracking as well. The mechanism for disseminating that information to department designates was not discussed.

The meeting was adjourned at 9:55 am.

Respectfully submitted,

Ann Wilson