

Institutional Review Board Minutes
May 3, 2007

Members Present: Allen, Evans, Finney, Gallacher, McCoy, Preiss, Ochosi, Wilson, Woodward

The meeting was called to order at 11:00 am in Wyatt 326.

Old Business

Protocol #0607-020 The investigators withdrew the protocol. No further action is necessary.

Protocol #0607-021 The investigators worked with the Chair over e-mail and the protocol was approved.

New Business

A student with an active protocol that met the requirements for expedited review by the Occupational Therapy department informed her research committee that she had not followed her protocol for determining inclusion criteria for her study. The deviation from the written protocol was that she did not score a written screening exam that would have excluded certain participants until after she had completed the study. As a result, two of the participants completed the study who should have been excluded. The student's research committee has determined that the student cannot include the data from those participants.

The student was asked to come before the full IRB to explain what happened and to articulate her understanding of the potential consequences to the integrity of the research process. She appeared with her committee chairperson and explained the deviation from the protocol and that she recognizes and acknowledges her error and the potential consequences to the integrity of the research process. The student was then excused and the committee agreed with the sanctions imposed by her research committee. No further action was taken by the board.

Modifications to Protocol #0607-002 were approved with suggestions for minor changes in wording of the child's consent/assent and a statement asking the parent or guardian to sign a HIPAA statement.

Modifications to Protocol #0607-005 were approved with suggestions for minor changes in wording on the consent form.

Protocol #0607-022 was approved with minor modifications to wording in the consent form.

Protocol #0607-023 was approved with modifications to the wording in the consent form and on the proposed recruitment flyer.

Protocol #0607-024 was approved with modifications to the wording in the consent form and further explanation as to which protected health information will be taken and how that information will be used.

Protocol #0607-025 was approved with modifications to the wording in the consent form and minor changes on the proposed recruitment flyer.

McCoy reviewed the charge from the Faculty Senate requiring that standing committees conduct a self-evaluation. In preparing for this discussion, McCoy met with Finney and Sarah Moore to discuss the major components of the evaluation. McCoy shared that Sarah Moore will assume the ex-officio administrative role currently held by Finney and that the Office of the Associate Deans is going to be adding additional administrative support staff that may be able to alleviate some of the burden currently borne by the chair.

The following issues were considered for the self-evaluation:

Committee size which was determined to be adequate

Frequency and timing of meetings which was determined to be adequate given the board's agreement to meet in the summer if necessary

Committee membership which was determined to be adequate provided that there is representation from a variety of academic disciplines, particularly those disciplines which routinely submit protocols for review.

Committee organization was determined to be adequate with respect to the selection of a chair, the role and responsibilities of the chair, the role of the ex-officio member, voting members and the possibility of having additional administrative support from office staff in the future.

Committee responsibilities were found to be appropriate with the exception of the current language which suggests that the IRB is also responsible for monitoring animal research on campus. Given that another group has those responsibilities; it was recommended that animal research be dropped from the description of the IRB which is designed to protect human subjects.

McCoy will prepare a report of the self-evaluation to submit to the Faculty Senate.

McCoy recognized all committee members for their respective contributions to the board for this year. John Finney was particularly recognized for his years of service on the IRB and he was wished well in his retirement. His calm demeanor and attention to detail will be sorely missed by everyone on the board.

The meeting was adjourned at 1:30 p.m.

Respectfully submitted,

Ann Wilson
Substitute Secretary