IRB Committee Minutes
5 May 2005

Members Present: Roger Allen, John Finney, Robin Foster, Kathi Lovelace, Lisa Ferrari, John Woodward, Pat Coogan, and Judith Kay

I. Old Business

IRB members approved the 7 April 2005 minutes.

II. Proposals Reviewed:

1. Protocol #0405-016: *(Note: This protocol was submitted after the April deadline and was reviewed individually by each IRB member, who then forwarded comments to the chair.)*

   The investigators made revisions to the protocol subsequent to the members' feedback; Roger and Judith will review these minor changes. The investigators still need letters of permission from Good Samaritan Hospital and from the pertinent school system. One member requested that the investigators spell out more clearly how they will make the judgment that a child's nonverbal cues would warrant stopping the trial. The subject's signature line should be deleted on the parental consent form. The child's consent form should be clearly marked "Consent Form" at the top.

   Decision: M/S/P approval pending revisions.

2. Protocol #0405-017: *(Note: This protocol was a modification and resubmission of a previously approved protocol.)*

   Decision: M/S/P approved with no revisions.

3. Protocol #0405-018:

   The sample size on page one should be 60 in order to match the cover sheet and page four. The investigators could advertise to female sport leagues in the city. The investigators need permission letters to post their flier. The phrase "audio and videotape" should be deleted under the confidentiality section in the consent form. It was recommended that under the risks and benefits section on the consent form a separate paragraph be made for the section dealing with the risks associated with the pelvic floor exercises. The investigators are reminded to ensure adequate attention to subjects' privacy when they complete questionnaires. The protocol should provide a rationale for asking sensitive questions listed in #12 on appendix C; the last item on that list might be changed to read, "Have you been diagnosed with an eating disorder?"

   Decision: M/S/P approved with proposed revisions.

III. New Business

A general discussion ensued about the committee's degree of monitoring. The IRB "follow-up questionnaire" and "guidelines for progress reporting" already address

this concern. The IRB almost never receives a protocol that it considers high risk. If the committee were to receive one, members could evaluate whether or not an alternative mode of research with a lower risk might be feasible. Consultation with the University legal counsel might also be an option with proposals deemed high risk. If the high-risk research were to occur at another institution, the IRB could check with that institution about its oversight and/or request information in the letter of permission about its oversight procedures. Perhaps some protocols with moderate level of risk could trigger a site visit for monitoring, if such were feasible given the institutions' personnel and resources. The IACUC already conducts site visits for protocols involving invasive techniques, such as injections or blood draws.

We have at least two other protocols to review this summer; our next meeting is 1:00 Tuesday May 17.

Roger will prepare and submit a final report to the Senate via Bill Beardsley.

The meeting adjourned at 1:15 p.m.

Respectfully submitted, 5-05-05

Judith W. Kay