

MINUTES
Institutional Review Board
May 11, 2010

Present: Garrett Milam (Chair), Lisa Ferrari, Mary Rose Lamb, Julia Looper, Grace Kirchner, David Lupher, Petra Perkins, and David Moore

Meeting was called to order at 10:05 a.m.

Announcements: Garrett reviewed the agenda for the meeting, which included deliberation on protocols 0910-106 and 0910-011 (modification), continued discussion of the University's Research Misconduct Policy, and the procedure for handling protocols submitted during the summer.

Orders of Business:

1. Deliberation on Protocol 0910-016. Key issues and questions included the following:

- One of the primary questions pertained to the proposed ECG readings and whether researchers will have adequate training and experience to competently administer and interpret the ECG patterns during the procedure itself. Of particular concern is whether the PI or other researchers conducting the study would be able to detect any unknown or undiagnosed cardiac problems of participants. If the PI has adequate training and experience in this procedure, this fact needs to be stated clearly. If not, an outside person should be brought in to administer this aspect of the study procedures.
- Given the need to attach ECG electrodes directly to bare skin, the researcher should explicitly describe in the consent form the ECG electrode attachment procedure, including where the electrodes will be attached.
- The researcher should indicate more clearly what will be said to participants if testing needs to be stopped (e.g., due to abnormal heart rhythm), in order to prevent being overly alarming to participants.
- The study flier needs to provide more specific information regarding what participants will be asked to do, so that participants can make a more truly informed decision about their willingness to participate.
- In the Consent Form at the bottom of page 2, please clarify the statement regarding future health information. Also, it may be better to make the stated location of data storage less specific (e.g., the office of the PI rather than the specific office number), especially given that the PT building will be torn down and replaced in a couple of years.

Action: The committee voted 8-0 for the proposal to be revised and resubmitted for electronic review by the full Board before final approval can be given.

- 2. Deliberation on Protocol 0910-011 (Modification).** The only change to the previously approved proposal involves expanding recruitment to additional sites besides local schools.

Action: The committee voted 8-0 to approve the proposal, pending submission of approval letters from the new recruitment sites before data are actually collected at those sites. These letters are to be submitted to the Chair of the IRB, Garrett Milam.

- 3. Review of the University's Research Misconduct Policy.** The Committee members briefly discussed the specific charge of the PSC regarding this policy and the expectation for the IRB to draft a revised document for the PSC to review. Given that this is the last regularly scheduled meeting of the semester, the Board decided that Chair Milam will communicate to the PSC the Board's assessment that some changes definitely need to be made to the Research Misconduct Policy and that the Board will take these up beginning in the fall, with the plan to report back to the PSC with a revised document. Since one of the necessary changes to the policy includes the need to reconcile this document with the Faculty Code, it may be helpful to have the PSC collaborate on this particular aspect of the Policy's revision.

- 4. Handling of Summer Protocols.** It was decided that the IRB will arrange meetings as necessary during the summer to review proposal submitted during the summer months, with the provision that at least 3 IRB members can be present. Those members unable to be present are requested to review protocols and submit feedback electronically, to the extent possible.

The meeting was adjourned at 11:00 a.m.

Respectfully submitted,

David Moore